

workshop report

# preventing postpartum hemorrhage

from research to practice





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editors Anne Pfitzer Harshad Sanghvi





The Maternal and Neonatal Health (MNH) Program is committed to saving mothers' and newborns' lives by increasing the timely use of key maternal and neonatal health and nutrition practices. The MNH Program is jointly implemented by JHPIEGO, the Johns Hopkins Center for Communication Programs, the Centre for Development and Population Activities, and the Program for Appropriate Technology in Health. www.mnh.jhpiego.org

JHPIEGO, an affiliate of Johns Hopkins University, builds global and local partnerships to enhance the quality of health care services for women and families around the world. JHPIEGO is a global leader in the creation of innovative and effective approaches to developing human resources for health.

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### ABBREVIATIONS AND ACRONYMS

AMDD Averting Maternal Death and Disability (Program)
AMTSL Active management of the third stage of labor

ANM Auxiliary nurse midwife

AOFOG Asia & Oceania Federation of Obstetrics & Gynaecology

BEOC Basic emergency obstetric care

BP/CR Birth preparedness/complication readiness

CI Confidence interval

CME Continuing medical education
CPR Contraceptive prevalence rate
CCT Controlled cord traction

DHS Demographic and Health Survey

EmOC Emergency obstetric care

IEC Information, education, and communication

FIGO International Federation of Gynecology and Obstetrics GNPRH Global Network for Perinatal and Reproductive Health

HM/HB Healthy Mother/Healthy Baby MCH Maternal and child health

MCPC Managing Complications in Pregnancy and Childbirth

MOH Ministry of Health MPS Making Pregnancy Safer MMR Maternal mortality ratio

NGO Nongovernmental organization
NSAID Nonsteroidal anti-inflammatory drug

NTT Number needed to treat

OR Odds ratio

ORS Oral rehydration solution

PATH Program for Appropriate Technology in Health PMTCT Prevention of mother-to-child transmission (of HIV)

PPH Postpartum hemorrhage

RHRC Reproductive Health Response in Conflict (Consortium)

RPMM Regional Prevention of Maternal Mortality

RR Relative risk

SEARO South East Asia Regional Office (of the World Health Organization)

TBA Traditional birth attendant

TFR Total fertility rate

USAID United States Agency for International Development

VHSP Village health support group WHO World Health Organization WRA White Ribbon Alliance

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Averting Maternal Death and Disability Program

**CARE** 

Chulalongkorn University

EngenderHealth

Family Care International

Gynuity Health Projects

International Confederation of Midwives

IntraHealth International

John Snow International

Pathfinder International

The Population Council

Program for Appropriate Technology in Health

Royal Thai Ministry of Health

UNFPA

UNICEF/India

University of California

University of Illinois

USAID/Afghanistan

USAID/Cambodia

USAID/Egypt

USAID/India

USAID/Indonesia

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World Health Organization/South East Asia Regional Office

World Health Organization/Western Pacific Regional Office

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## PREVENTING POSTPARTUM HEMORRHAGE: FROM RESEARCH TO PRACTICE

#### **OVERVIEW**

From 20 to 23 January 2004, the JHPIEGO/Maternal and Neonatal Health (MNH) Program and the Asia/Near East (ANE) Bureau of the United States Agency for International Development (USAID) held a conference in Bangkok, Thailand, to review the evidence for approaches to preventing postpartum hemorrhage (PPH) and explore strategies for scaling up interventions in the field (see **Appendix A** for the conference agenda). One hundred twenty-six participants, from Sweden, the United States, and the following 13 Asian countries, attended the meeting:

Afghanistan Nepal
Bangladesh Pakistan
Cambodia Philippines
Egypt Thailand
India Vietnam
Indonesia Yemen

Myanmar

Participants were policymakers and program managers from ministries of health at national and subnational levels; researchers; clinicians; faculty from medical, nursing, and midwifery schools; inservice trainers; and leaders of nongovernmental and international donor organizations. In addition, representatives from the World Health Organization (WHO) UNICEF, and USAID global and regional offices and missions were present (see **Appendix B** for a complete list of workshop participants).

The overall goal of the conference was to move evidence-based interventions for preventing PPH into common practice. Although some proposed approaches involve the clinical management of childbirth, others deal with community-based efforts to raise awareness and empower families and their communities to action when women experience complications. The objectives of the meeting were to:

- Review the evidence supporting strategies for prevention of PPH in settings where skilled birth attendants may or may not be available
- Examine best practices for implementing large-scale programs for preventing and treating PPH
- Develop action plans to prevent and treat PPH using evidence-based approaches and best practices

Severe bleeding after childbirth is the largest cause of maternal mortality, accounting for at least one-quarter of maternal deaths worldwide. An

estimated 550,000 women die every year of maternal causes. Among these, an estimated 125,000–150,000 deaths are from PPH. In Asia, PPH contributes to an even higher proportion of maternal mortality, and some countries report that as many as 45% of maternal deaths are linked to PPH (WHO 1996).

Several of the speakers during the conference's opening ceremony quoted Dr. Mahmoud Fathalla, former president of the International Federation of Gynecology and Obstetrics (FIGO) and a strong advocate for safe motherhood. He said:

Women are not dying because of diseases we cannot treat...they are dying because societies have yet to make the decision that their lives are worth saving.

Leon Waskin, Acting Mission Director from the regional USAID office in Bangkok, noted that although this powerful statement points to one of the root problems in addressing maternal health, the positive note for the future is that there are solutions—there are specific steps that will reduce maternal mortality significantly. This conference delved into solutions for preventing and managing PPH.

The concentration on PPH is not intended to encourage programs that are focused narrowly on PPH, but to highlight a major cause of maternal death and, more specifically, call attention to what policymakers, educators, providers, and community members can do to prevent it.

Dr. Lily Kak, Maternal Health Advisor, USAID/Washington, noted in her remarks at the opening session that the international community has met several times since the Safe Motherhood Conference in Nairobi in 1987 in an attempt to galvanize the world to reduce maternal mortality, without a significant or perceptible reduction in the statistics to date. In September 2000, at the United Nations Millennium Summit, the United Nations set a goal of reducing the maternal mortality ratio (MMR) by three-quarters between 1990 and 2015.

In 2003, USAID developed a special initiative for preventing PPH in response to new evidence that low-cost, feasible interventions exist. This initiative seeks to ensure that proven interventions are included in existing and ongoing maternal health programs. Through this special initiative, USAID approached FIGO and the International Confederation of Midwives (ICM) for support. As a result of these efforts, the two societies joined together to launch their own initiative for preventing PPH during the FIGO meeting in Santiago, Chile, in November 2003. Their *Joint Statement on the Prevention of Postpartum Hemorrhage* and *Call to Action* serve as powerful tools to enlist national professional organizations to join the cause of preventing PPH (see **Appendix C**).

#### SAFE MOTHERHOOD: TAKING INNOVATIONS TO SCALE

## **Keynote Speech by Dr. Noel McIntosh, President of JHPIEGO**

"The world in general doesn't know what to make of innovation; it is startled out of its comfortable habits of thought [and behavior], and its first reaction is often one of anger."

W. Somerset Maugham

(1874 - 1965)

Taking innovations to scale is a complex and poorly understood process—one that requires time, money, leadership, and commitment. Risks, both professional and personal, are involved for those who champion innovations. It requires a special kind of person to advocate for taking innovations to scale.

Given the challenge of scaling up innovations, careful thought should be given to whether an innovation is worth applying widely.

Taking innovations to scale requires at least three distinct, but linked, processes:

- Identifying best research findings (potential innovations). There is a considerable body of literature on research utilization that provides ideas, theoretical basis, and practical guidance on ways to identify best practices.
- Transferring research to practice. How well does the innovation apply outside the research setting? There is much less literature on how research can influence health services or practices.
- Taking the practice to impact. The use of the practice must be expanded sufficiently that its impact affects the general population.

Because donor organizations are demanding more return on their investment and need to show that their programs have impact, nearly all are attempting to identify those research findings most suitable for transfer to practice. An emerging problem now is that there are far too many good research findings to be transferred to practice. Unfortunately, highly significant research results with high odds ratios do not alone warrant scaling up a new innovation. Indeed, new mechanisms are needed beyond meta-analyses and randomized clinical trials to help health policymakers and donors assess the potential value of new research findings. This would include understanding what it takes to transfer an intervention into practice—the costs and difficulty—as well as a clear understanding of the benefits, and an examination of potential long-term consequences of implementing the innovation. The eradication of smallpox and subsequent use of poxvirus for bioterrorism provide an example of an unintended consequence of taking an innovation to scale.

Currently, health policymakers are drowning in an ever-increasing sea of data. For example, more than 60 risk factors for developing prostate cancer have been identified, each documented in well-designed randomized controlled trials, yet in total they account for only about 20% of the new cases. In reproductive health, and especially maternal and newborn health, data dumping is a major problem. Practically speaking,

in the 48 poorest countries, only about 10% of new research findings may be worth considering for transfer to practice; even less (1-2%) are related to interventions that have the potential to be scaled up to achieve health impact.

Under ideal conditions, researchers, policymakers, and donors would all work together, keeping one another informed of potential innovations, their policy implications, and the funding situation. These three groups would also have an open communication channel with stakeholders in the field—communities and frontline providers—so that applying these innovations in the field, through existing projects, local budgets, and training programs, would make implementation a seamless process. In this scenario, researchers understand that decision-making is a process rather than an event; contribute to framing the problem and setting limits on feasible options; and work to accommodate funding and resource constraints. Policymakers understand the research process and limitations. Donors are sensitive to local stakeholders' ideas and concerns and avoid pushing too hard.

This ideal rarely exists. Too often, researchers and policymakers communicate infrequently or late in the process (e.g., after the researcher has completed a study and is brandishing new data, or when a policymaker has already decided on a solution). Researchers and public health professionals who ignore the distinction between politically sensible and rational decisions (i.e., fail to acknowledge and accept the influence of political and institutional factors) will have a difficult time gaining access to the decision-making world. Having a better understanding of the key elements in the decision-making process will help researchers and public health professionals understand the distinction between rational and sensible decisions, and the importance of knowing not only whether, but also how and when, a new innovation might be useful or acceptable. For example, there are both formal and informal institutional structures for decision-making. Values of decisionmakers, such as their interests, ideologies, current information, and beliefs (in particular, about how scientific knowledge explains the world), play an important role. Among these values, only beliefs are influenced by research findings, and beliefs seldom change quickly. Although the decisions may not always seem rational to others, in a political context they are sensible.

Similarly, donors too often push hard to support the latest global innovation, with little consideration for the need to conduct local operations research or programmatic assessments at the district or community levels. Typically, implementing global research findings (e.g., benefits of oral rehydration solution [ORS], immunization, or polio eradication) is the most difficult because by nature the process is usually top-down (outside push) and less participatory, and bypasses opportunities to gain local support. Success in implementing them depends on having a secure, long-term funding stream and identifying settings in which the findings are appropriate and perceived to be useful.

"In the absence of special efforts to foster the use of research results, chances of rapid uptake of findings are minimal [because] they depend on the haphazard collision of new information in a rising sea of data onto an interested policymaker who finds that the information:

- might address a need in her/his local setting, and
- has the resources to act on that interest."

Matthew Tiedemann, 2003

This is necessary in order to create "pull" or demand for the innovation (Lomas 2000; Rogers 1995; Schroeder et al. 1986).

New innovations that ultimately reach widespread use—such as family planning in the 1960s or ORS in the 1980s—generally follow a typical pattern over time. This pattern is characterized by a start-up phase that may take several years before the innovation begins to be accepted or used. During this early phase, only a small percentage of potential users may be reached. With time, however, as more people become familiar with the innovation, the percentage of users starts to rise very dramatically. The point between these two phases (i.e., the intersection of the slow and rapid phases), which usually occurs when usage (or acceptance) of the innovation is at the 15–20% level, is called the *tipping point*. From then on, the rate of increase usually is quite rapid, finally slowing only when the 80–95% level is reached (Gladwell 2000; Rogers 1995).

This pattern of slow start-up followed by an increasing rate of acceptance was first demonstrated in the 1940s by Ryan and Gross, who charted the pattern of acceptance of a new hybrid corn seed by Iowa farmers (Ryan and Gross 1943). Since then, it has been demonstrated repeatedly in many fields (e.g., engineering, architecture, manufacturing, and even healthcare). The spread of family planning use in countries such as Thailand and Indonesia, which both ultimately achieved high contraceptive prevalence rates (CPRs), is a good example of this phenomenon. In these two countries, and many others as well, contraceptive use rose slowly until the CPR was about 15–20%. Then, because funding was adequate, there was strong support by the government, and clients had ready access to services, the CPR began to increase rapidly. In Thailand, it did not begin to level off until the CPR was at the 60–70% level, and the desired goal of a stable population was reached.<sup>2</sup> Unfortunately, the CPR in Indonesia slowed considerably after reaching the 50–60% level in the late 1990s, and for multiple reasons has not risen much since then. As a consequence, the fertility rate, though considerably reduced (2.35), remains above replacement levels (Berwick 2003).

In the family planning context, getting a national program to the 15–20% usage level is the most difficult part of taking an innovation to scale. Thereafter, the program often seems to take on a life of its own and will continue to grow unless funding or other essential factors that promote utilization are insufficient. Conversely, innovations that are "pushed" from the outside or have little stakeholder support (minimal perceived benefit, too complicated, too risky, or inconsistent with values or interests of users or providers) usually do not reach the tipping point and ultimately will not have impact.

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<sup>&</sup>lt;sup>1</sup> Gladwell M. 2000. The Tipping Point: How Little Things Can Make a Difference. Little, Brown and Company, Boston, MA.

<sup>&</sup>lt;sup>2</sup> Today, Thailand's contraceptive prevalence rate is 72% (any method) and the total fertility rate is 1.93, which is below replacement levels.

Depending on the nature of the innovation, impact will begin to have significance at 45–55%. In the family planning example, this level of contraceptive prevalence will result in lower total fertility and child mortality rates. In other cases, large-scale health impact may not occur until the intervention reaches 70–80% of potential users. For example, for immunizations, 80% coverage is considered the minimum level to prevent epidemics (Gladwell 2000).

The characteristics of adopters of a new innovation have also been studied quite extensively. For example, Berwick (2003) recently reviewed the work by Ryan and Gross (1943) and Rogers (1995), who identified five types of adopters: innovators, early adopters, early majority adopters, late majority adopters, and laggards. This classification system is based on their distribution around the mean of the rate of adoption curve (Rogers 1995).

Innovators are a small group who will experiment, invent, and adopt a completely new technology or approach if they believe it has merit. These individuals have a high tolerance for risk and a keen interest in learning, and are often wealthier than the average, but can appear socially disconnected. They are definitely not opinion leaders, as they are considered too incautious and outlandish. In the health sector, they are considered mayericks.

The next group, the **early adopters**, will show an interest in an innovation already tested by an innovator and will be quick to adopt it. They represent about 13% of adopters. They are different from innovators, in that they are opinion leaders, socially well connected, and respected. They also interact with innovators in order to select ideas to try. They have the resources and willingness to venture into using new approaches. Most importantly, this is the group that the remaining three groups watch and follow.

The early majority adopters represent 34% of the total and look for reassurances from the early adopters that an innovation is safe to use. The more conservative late majority adopters (also about 34%) will adopt an innovation only when it becomes the standard of practice. For example, they represent those physicians and health professionals who require local proof, as they do not trust outside sources of knowledge.

Finally, the last group, the **laggards**, represents about 16% of the total adopters. They might more appropriately be referred to as **traditionalists**. They are wise and useful to the community. In health, they are the physicians who swear by the tried and true and accept change only slowly.

Another important point on the rate of adoption curve is the **transition point**. This is the point on the curve (at about the 50–60% level) where the innovation should be fully integrated into its environment (e.g., the healthcare system). When acceptance of a new innovation reaches this

point, all operating costs should be funded by incountry sources, training should be incorporated into the preservice educational system, and supervision and monitoring systems should be in place and operational. Without this integration, the program may stall for lack of resources (financial, physical, and/or educational), as is the current situation in Indonesia with family planning.

Different interventions may see different rates of adoption. One example of a rapid rate of adoption is the use of nevirapine for the prevention of mother-to-child transmission of HIV (PMTCT). An initial study using an antiretroviral for PMTCT was reported in 1994, but that study was conducted in the United States. The treatment protocol was long and complicated and the babies were treated for 6 weeks following birth. Then, in 1999, a Ugandan randomized clinical trial demonstrated results with a simpler regimen. Subsequently, the Uganda findings were quickly confirmed (in less than 2 years), and external funding became available to rapidly start 50 demonstration programs, largely in sub-Saharan Africa (Wright 2003).

In contrast, certain innovations can take a very long time to reach impact. For example, Captain James Lancaster conducted an experiment with lemon juice in 1601. The men on the ships in the intervention group all survived long ocean journeys, whereas 40% of those in the ships without the lemon juice died of scurvy. It was not until 1865, nearly 250 years later, that the British Board of Trade established a policy requiring that lemon juice be given to sailors on long journeys. Two reasons for the lag were that communication of these results was hampered, and that many of Captain James's compatriots did not believe the results. Ultimately, there was no champion for the intervention until 1747, when James Lind repeated the experiment. Even so, change was slow (Berwick 2003).

How policymakers, community members, and stakeholders perceive innovations is the most important and influential factor in bringing about change. This single factor influences 49–89% of the variance in the rate of adoption. The following factors also influence early adoption (Rogers 1995; Ryan and Gross 1943):

- Whether the innovation is consistent with values, beliefs, and current needs
- The simplicity of the innovation
- Adaptability of the innovation and how readily it can be modified to fit local conditions
- Observability or how easily potential adopters can observe the innovation being used

Finally, other factors that may facilitate adoption include the strength, quality, and trustworthiness of the research findings; the anticipated public health impact of the innovation; and its cost-effectiveness.

"A maternal death is a quiet death. There is no constituency for the victims of maternal deaths. Grassroots movements, such as the White Ribbon Alliance, which is now global, can and are helping create a broader base of support for maternal and neonatal health services. But for the short term, taking maternal and neonatal health interventions to scale will have to be driven largely from within—through the efforts of government policymakers and community-level stakeholders in each country."

Dr. Noel McIntosh, JHPIEGO, Keynote Speaker Limiting factors include the lack of an organized constituency and competing health problems and priorities (e.g., the overarching impact of the HIV/AIDS epidemic).

These factors come into play when an innovation is proposed. Who makes the proposal is also important, as is whether a maverick or an opinion leader promotes the idea. If the idea is being promoted externally (such as external donors promoting family planning in the 1960s and 1970s or PMTCT now), external funding may be necessary for many years to fuel the rate of adoption.

## REVIEW OF THE EVIDENCE REGARDING PREVENTION OF POSTPARTUM HEMORRHAGE

#### **Epidemiology of Postpartum Hemorrhage**

Dr. Monir Islam, Director of Family and Community Health at the WHO/South East Asia Regional Office (SEARO), reviewed the epidemiology of PPH.

Globally, 200–210 million pregnancies occur every year, of which 515,000–600,000 result in a maternal death. Ninety-nine percent of these deaths are in developing countries. Roughly 150,000 of these deaths result from bleeding complications, and in most cases there were no identifiable risk factors. The great majority of PPH cases result from uterine atony, a condition in which the uterus fails to contract after delivery of the fetus and/or placenta (WHO 1996).

These global figures and statistics mask great variations among countries. In the South East Asia subregion, the MMR ranges from 35 maternal deaths per 100,000 live births in South Korea to 830 per 100,000 in Nepal. Although PPH accounts for 24% of the causes of maternal deaths globally, it causes 23% of deaths in India and 35% in Sri Lanka. India has a MMR of 440 per 100,000 live births, while Sri Lanka's maternal mortality is low (60 per 100,000). Countries that have made great strides in improving their health systems often see a higher percentage of deaths from PPH because they may have successfully reduced deaths from other causes. Indeed, trend lines related to maternal deaths due to PPH in Thailand strikingly illustrate this point. From 1997 to 2001, the proportion of deaths attributable to PPH rose from 23% of all deaths to 42% of deaths, even while the MMR went down to 44 per 100,000 (WHO 1996).

Regional variations in statistics are repeated when we examine subnational statistics. Thailand's northern and southern regions have much higher MMRs than Thailand's other two regions. In India, states such as Kerala and Goa have managed to reduce maternal mortality, while others have not. Beyond geographical variation, there are differences among economic classes. In Tamil Nadu, 33% of women in

"Poor countries are not rich enough to invest in all solutions; our countries need appropriate solutions." Dr. Monir Islam, WHO/SEARO the poorest quintile give birth at home, while only 8% of the richest women do. Regionally, those who give birth at home are most likely to do so alone or with relatives, rather than with a skilled provider or even a traditional birth attendant (TBA). Statistics from Bangladesh, India, Indonesia, and Nepal underscore the WHO premise that training TBAs is not an effective use of resources. In India, 8% of women give birth with a TBA, while 52% give birth with neither a TBA nor a skilled provider. Generally, maternal mortality is lower in countries where a higher percentage of women use a skilled provider. Indeed, skilled care is essential to prevent and manage PPH. Providers must also have the necessary tools and supplies at their disposal to be effective. Without basic drugs and supplies, even an obstetrician/gynecologist will be helpless in the face of a serious complication such as hemorrhage.

#### **Active Management of the Third Stage of Labor**

Dr. Harshad Sanghvi, Medical Director for the MNH Program at JHPIEGO, provided an introduction to and overview of active management of the third stage of labor (AMTSL).

Active management of the third stage of labor is an evidence-based means of preventing PPH. Dr Sanghvi stressed the importance of prevention, as there are no predictive factors for PPH. In almost all cases, hemorrhage comes as a complete surprise. Thus, every woman should benefit from available preventive measures.

The physiologic evolution of labor is characterized by distinct phases or stages. The third stage consists of the expulsion of the placenta and begins immediately after the birth of the baby. Typically, the muscles of the uterus contract and the placenta begins to separate from the uterine wall until it is eventually expelled. The amount of blood loss depends on how quickly this stage occurs. In uterine atony, the uterus does not contract normally. Blood vessels at the placental site do not tighten, and severe bleeding results.

Active management of the third stage of labor is differentiated from physiologic (or expectant) management. In the latter, the normal physiologic processes are allowed to take place without intervention for a certain period of time. The placenta is delivered by gravity or maternal effort. In contrast, active management calls for:

- administering uterotonics as soon as possible after the anterior shoulder of the baby is born,
- clamping the cord within a minute of the baby's birth, and
- applying controlled cord traction (CCT) along with counter-traction on the uterus during uterine contractions.

In practice, clinicians often use variations of both physiologic and active management. In some cases of expectant management, the uterus is massaged to encourage contractions, or there is pulling of the cord following the rush of blood that accompanies the separation of the placenta, or pressure is applied to the uterus to speed the delivery of the placenta. Similarly, in AMTSL, the route of administration and the type of uterotonic can vary, or there are delays in clamping the cord or in the initiation of CCT. An additional element of AMTSL involves rubbing the fundus after placental delivery to ensure contractions.

As described in the WHO reference manual Managing Complications in Pregnancy and Childbirth: A Guide for Midwives and Doctors, the procedure of AMTSL includes the following steps:

- Place the baby on the mother's abdomen.
- Thoroughly dry the baby, wipe the baby's eyes, and assess the baby's breathing.
- Clamp and cut the umbilical cord.
- Palpate the mother's abdomen to rule out the presence of another baby.
- Within 1 minute of birth, give oxytocin 10 units intramuscularly.
- Await strong uterine contractions (2–3 minutes).
- Apply CCT while applying counter-traction above the pubic bone.
- If the placenta does not descend, stop traction and await the next contraction.
- After placental delivery, rub the fundus of the uterus gently every 15 minutes for 2 hours to ascertain that it is contracted.<sup>3</sup>

Experiences around the world in training providers in this technique have shown that compliance in administering oxytocin within 1 minute and applying CCT is maintained after training. The more inconsistent step is that of monitoring the uterus for 2 hours postpartum. Also, many providers express concerns about the cost of using oxytocin for every birth.

There are concerns about whether early cord clamping reduces newborn hemoglobin levels; however, most clinicians believe that 1 minute allows sufficient time for umbilical cord blood to transfer to the newborn. Before reviewing the literature, Dr. Sanghvi highlighted the difficulties and potential discrepancies associated with measuring blood loss after childbirth: blood may be mixed with maternal liquor, urine, and cleansing solutions used by providers. When collected, blood may be soaked on swabs, gauze, towels, or linen. It may splash on surfaces or drain from the placenta or cord and be difficult to collect. In the literature, there are varying and inconsistent durations for collection of blood following

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<sup>&</sup>lt;sup>3</sup> World Health Organization (WHO). 2000. Managing Complications in Pregnancy and Childbirth: A Guide for Midwives and Doctors. WHO: Geneva.

childbirth, with collection ending a few minutes to a few hours postpartum. Some of the blood loss may be due to iatrogenic procedures, such as episiotomies. Clinical estimates of blood loss, where no special efforts are made to physically measure blood loss, are generally thought to be underestimated by 34–50% (Prendiville, Elbourne, and McDonald 2004).

The following table describes results reported in the Cochrane Review, comparing active versus expectant management:

Table 1. Comparison of Blood Loss Using Active versus Expectant Management of the Third Stage of Labor

MANAGEMENT OF THIRD STAGE	BLOOD LOSS* >500 ML	BLOOD LOSS* >1000 ML
Expectant (n=3126)	13.6%	2.6%
Active (n=3158)**	5.2%	1.7%
Relative Risk	0.38 (CI 0.32-0.46)	0.33 (CI 0.21-0.51)
Number Needed to Treat (NTT)	12 (CI 10-15)	57 (CI 42-89)

Source: Prendiville, Elbourne, and McDonald 2004.

With reference to the number needed to treat (NTT), **Table 1** shows that for every 12 women provided with active management, one case of PPH is averted. <sup>4</sup> Compared to other preventive measures, such as vaccines, the number to treat shows high effectiveness.

In two other trials, the rate of PPH was significantly lower with active management than with physiologic management: 5.9% vs. 17.9% (Prendiville et al. 1988) and 6.8% vs. 16.5% (Rogers et al. 1998).

These two trials are also thought to provide evidence regarding concerns that active management raises potentials risks of placental entrapment, avulsion of the cord, uterine inversion, and, as mentioned above, newborn anemia. **Table 2** indicates that, for maternal outcomes, these concerns are unfounded:

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<sup>\*</sup> Clinical estimations of blood loss used, which are often underestimated

<sup>\*\*</sup> Oxytocin, ergometrine, or both used intramuscularly or intravenously

<sup>&</sup>lt;sup>4</sup> Given that the clinical definition of PPH is an estimated 500 ml blood loss.

Table 2. Results of Two Studies on the Duration of the Third Stage of Labor, Need for Blood Transfusions, and Use of Therapeutic Oxytocics by the Type of Management of Third Stage

CLINICAL FACTOR/ INTERVENTION	STUDY	ACTIVE MANAGEMENT	PHYSIOLOGIC MANAGEMENT	ODDS RATIO AND 95% CI
Duration of 3 <sup>rd</sup> Stage	Bristol	5 minutes	15 minutes	
(median)	Hinchingbrooke	8 minutes	15 minutes	
Third Stage Less than	Bristol	25 (2.9%)	221 (26%)	6.42 (4.9–8.41)
30 Minutes	Hinchingbrooke	25 (3.3%)	125 (16.4%)	4.9 (3.22–7.43)
Blood Transfusion	Bristol	18 (2.1%)	48 (5.6%)	2.56 (1.57–4.19)
	Hinchingbrooke	4 (0.5%)	20 (2.6%)	4.9 (1.68–14.25)
Therapeutic	Bristol	54 (6.4%)	252 (29.7%)	4.83 (3.77–6.18)
Oxytocics	Hinchingbrooke	24 (3.2%)	161 (21.1%)	6.25 (4.33–9.96)

Adapted from: Prendiville et al. 1988; Rogers et al. 1998.

By definition, a retained placenta occurs if the duration of the third stage of labor exceeds 30 minutes. In the table above, there was no statistical difference in the incidence of retained placenta between the two types of management.

Evidence published in the literature strongly supports the use of AMTSL. Nevertheless, problems remain in translating the evidence into practice. Clinical guidelines and standards often do not include AMTSL as the standard. But even where AMTSL is the documented standard, supervision to encourage compliance does not exist. In Asia, only 68% of providers use some elements of active management (Festin et al. 2003), and episiotomies are performed routinely.

Dangerous practices, such as applying fundal pressure and recapping needles used for administering oxytocin, persist. In many countries, nurses and midwives are not allowed to give injections, precluding them from administering oxytocin. Supplies of oxytocin, syringes, and needles may be inadequate. Finally, oxytocin is not heat stable and may degenerate from poor storage conditions.

#### **Overview of Uterotonic Drugs**

Dr. Matthews Mathai, Professor and Chair of the Department of Obstetrics and Gynecology at Christian Medical College in Vellore, India, presented an overview of uterotonic drugs used for prevention of postpartum hemorrhage.

There are three types of uterotonics:

- Oxytocin
- Ergot alkaloids such as ergometrine or methylergometrine (methergine)

• Prostaglandin analogues, such as natural PGE2 and PGF2α; synthetic derivatives, such as sulprostone or carboprost; and PGE analogues, such as misoprostol

Oxytocin, which acts on receptors in the uterus, is a naturally occurring peptide from the pituitary gland. It increases the force and frequency of uterine contractions, as well as the alveolar myoepithelium of the breast to eject milk. Oxytocin is used to induce or augment labor, as well to manage the third stage and treat hemorrhage. It is usually administered intramuscularly or intravenously, but there are also buccal preparations. Oxytocin may cause water retention, vasodilatation, and hypotension and thus is contraindicated in the case of heart or kidney disease.

Ergot alkaloids are longer acting than oxytocin and cause forceful and sustained contractions. As a result, they are used only after fetal expulsion. They are usually administered intramuscularly or intravenously. However, oral preparations are insufficiently effective, with only 5% less blood loss than placebo (de Groot 1996). Ergometrine results in more frequent side effects, such as nausea and vomiting, muscle pains and leg weakness, and problems such as hypertension and coronary ischemia. Therefore it cannot be used in women with diagnosed preeclampsia or heart disease. Retained placenta is also more common when ergometrine is given early.

Prostaglandins act both on the uterus to cause contractions and on the cervix where they have been used to cause cervical ripening. It is available in intramuscular, intravenous, oral, vaginal, and rectal preparations, although the latter have not yet been sufficiently studied for obstetric uses. As with oxytocin, PGE2 prostaglandins can result in vasodilatation and hypotension. In addition, they often cause fever. PGF2 $\alpha$  increases the heart rate, blood pressure, and cardiac output.

Comparative studies of oxytocin and ergometrine show no differences in the incidence of PPH, but do show that the need for manual removal of the placenta decreases if oxytocin is given before placental expulsion (relative risk 0.57; 95% CI 0.41–0.79) (Elbourne et al. 2004). Syntometrine, a combination of oxytocin and ergometrine, offers fewer cases of PPH than oxytocin alone; however, it results in a 2.8 times higher incidence of elevated diastolic blood pressure and 4.86 times more frequent vomiting (McDonald, Prendiville, and Elbourne 2001).

Injectable prostaglandins are associated with reduced blood loss in the third stage of labor, with an average difference of -70 ml (95% CI -73 to -67 ml) when compared to injectable oxytocin. Injectable prostaglandins commonly have more side effects than injectable oxytocin, such as vomiting (odds ratio [OR] 10.70), diarrhea (OR 6.70), and abdominal pain (OR 5.00). Despite reduced blood loss, there were no significant differences in cases of PPH, the need for additional therapeutic oxytocics, or manual removal of the placenta (Gülmezoglu et al. 2004).

In tropical climates, ergometrine is especially vulnerable to deactivation by heat and light. In a survey of 100 field samples from five tropical countries, only 32 had 90–100% of the active ingredient, and 34 samples had less than 60% of the active ingredient. In the same survey, five field samples of oxytocin were tested for activity. One sample contained 107% and the others 112–142% of the stated amount of active ingredient (Hogerzeil and Walker 1996). Oxytocin is more stable but will still deteriorate when exposed to heat (above 30°C) over prolonged periods.

Dr. Mathai compared the price of oxytocin, methergine, carboprost (with disposable syringe and needle), and misoprostol in India. Ten units of oxytocin were the least expensive among the types of uterotonics available for the prevention of PPH.

Although a combination of oxytocin and ergometrine is more effective than oxytocin alone, this should be weighed against the more common adverse effects associated with ergometrine, which is contraindicated in women with hypertension. Intramuscular prostaglandins are not preferable to conventional injectable uterotonics. Both oxytocin and ergometrine are sensitive to light and heat and require cold chain management to preserve activity, but ergometrine deteriorates more rapidly than oxytocin. Where a skilled provider is present and oxytocin has been stored appropriately, oxytocin is the drug of choice for PPH prevention.

#### **Provider Practices Regarding Prevention of PPH**

Dr. Mario R. Festin, Professor of Obstetrics and Gynecology and Clinical Epidemiology at the University of the Philippines, presented the results of an international survey on variations in practice of the management of the third stage of labor (Festin et al 2003).

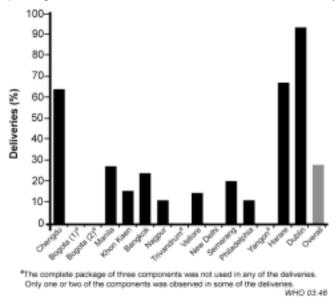
The survey's objectives were to determine the frequency of the use of AMTSL at centers that are part of the Global Network for Perinatal and Reproductive Health (GNPRH), including those in developing countries where PPH would be considered a more serious problem, and to determine whether evidence-based best practices were being used. The GNPRH focuses on improving maternal and perinatal health outcomes by using evidence-based clinical practices. The survey covered 14 university-based referral obstetric centers participating in the GNPRH. Two of these centers are located in developed countries (Ireland and the United States), while the rest are in seven different developing countries (Colombia, India, Indonesia, Myanmar, the Philippines, Thailand, and Zimbabwe). In each center, approximately 30 women participated in the survey. Standard data collection forms were used and reviewed by the investigator in each center before being analyzed by computer in one central location. The data forms collected information on frequency of use of uterotonics during childbirth, CCT, and early cord clamping, as well as client chart data. Overall, there were significant intra-country and inter-country variations in the practice of AMTSL. Active management

was practiced in only 24.6% of births (111 out of 452). This finding confirmed the existence of a large gap between knowledge and practice.

As shown in **Figure 1**, the Dublin center had almost universal practice of all three components of AMTSL. At the other extreme, there were five centers wherein no women received the complete package, although some centers did use one or two of the components. In all, 44% of the centers used uterotonics. There was some variation between oxytocin and ergometrine or in combination, with only limited use of prostaglandins; there were also differences in the route of administration of uterotonic drugs. Early cord clamping was practiced in 79.2% of the centers, and 70.1% of the centers routinely applied CCT. The survey also looked at the methods used by various centers to measure blood loss. In the great majority of cases (86.5%), clinical estimates of bleeding following birth were used. As noted previously, this method is inexact and results in underreporting of postpartum hemorrhage. Blood volume was measured in 10.2% of centers. In the remaining 3.3% of centers, blood was weighed to estimate postpartum bleeding.

Figure 1. Deliveries Having All Three Components of the Third Stage of Labor

The practice of early cord clamping was interrupted in Yangon during the period of this survey, due to the assessment of an intervention that involved placing the infant on the mother's abdomen immediately following delivery.



Source: Festin et al. 2003. International survey on variations in practice of the management of the third stage of labour. Bulletin of the World Health

Organization 81(4): 286-291.

## CHANGING PROVIDER PRACTICES: PROMOTING ACTIVE MANAGEMENT OF THE THIRD STAGE OF LABOR

## Training in Active Management of the Third Stage of Labor

#### **Indonesian Context**

- MMR: 307/100.000
- 180,000 deaths per year
- 70–80% of pregnant women are anemic
- 66% of births are attended by a skilled provider (Indonesia DHS 2003)
- PPH accounts for 28% of maternal deaths
- 80,000 midwives
- 1,215 midwifery schools

Ms. Asmuyeni Muchtar, midwife and JHPIEGO clinical specialist, discussed applying the evidence for AMTSL in Indonesia.

Ms. Muchtar presented strategies implemented in partnership by the Ministry of Health (MOH), the Indonesian Midwives Association (IBI), and the MNH Program.

The Government of Indonesia has long been committed to addressing maternal mortality. In the 1980s, the Mother Friendly Movement, which led to the placement of community midwives in Indonesian villages, was established. For the past 6 years, USAID assistance in maternal healthcare through the MNH Program has specifically focused on preventing PPH. Active management of the third stage was central to this effort.

The MOH, along with professional organizations, successfully updated, launched, and disseminated new national standards and guidelines. These guidelines are based on the WHO's Managing Complications in Pregnancy and Childbirth (MCPC) and include detailed steps for AMTSL. To translate the guidelines into practice, the MNH Program/Indonesia supported frequent and extensive dissemination events held by the MOH and professional organizations. A group of Indonesian midwives and obstetrician/gynecologists, developed as MNH Program experts, led the dissemination process. They conducted 3-day knowledge updates in national and provincial workshops covering all 32 provinces. Provincial representatives were encouraged to organize their own dissemination events for their districts with guidelines orientation packets.

In addition, curricula were updated both for inservice training and preservice education in midwifery schools. To ensure that training in AMTSL was effective, selected clinical practice sites used in both inservice and preservice training were strengthened. Training did not begin until these sites met a minimum level of compliance with national standards. In midwifery schools, clinical learning laboratories were established to allow students to acquire and practice new skills on anatomic models, using learning guides and checklists. Teachers and clinical instructors were trained in active management and other basic skills. Supervision and monitoring of clinical services were strengthened within district-level departments of health.

A similar process was used to establish state-of-the-art inservice training. A 10-day course in normal childbirth care was developed. An initial group of providers had their skills standardized; then they were followed and assessed regularly until they had brought their sites into compliance

with the standards. Then these providers were prepared as trainers and supervised as they developed their training skills.

## **Elements of Training** for AMTSL

- Explanation by trainer/clinical instructor and discussion
- Demonstration by trainer/clinical instructor and discussion
- Participants practice on anatomic model, following a learning guide
- Participants practice in clinical setting after they are competent on model
- 24 hour call for births during training

In addition to guidelines dissemination, training, and supervision, the MNH Program/Indonesia implemented an array of behavior change interventions to increase use of skilled providers at birth and to promote birth preparedness and complication readiness (BP/CR). One such intervention was the use of radio vignettes to educate midwives on various topics of maternal and newborn health, which were intended to reinforce and sustain the knowledge imparted during preservice education and inservice training.

During the lifespan of the MNH Program/Indonesia, the inservice training model has been successfully replicated and scaled up. Although the MNH Program/Indonesia focused on three districts of one province, other programs (including AusAid, UNICEF, UNFPA, World Bank, and the WHO) have adopted the model. Currently, the 10-day normal childbirth care course is delivered in 14 districts of five provinces, although participants from additional districts and provinces have also been trained. In some provinces, local or national government funds were used to replicate the MNH Program approach. The training was buttressed by professional organizations—both the obstetrics/gynecology society and the midwives' association. The course has been so well received that some midwives are paying their own costs to attend the course.

Ms. Muchtar concluded that teaching seemingly simple maternal and newborn health skills requires a complex set of inputs. She shared lessons learned from the Indonesia program, including the fact that it is better to select small but busy birthing homes as clinical practice sites, as they are easier to work with than hospitals. In addition, programs can save time and resources by selecting sites whose location allows them to be used for both preservice education and inservice training. Finally, in order for skills to be effectively modeled and transferred to learners, clinical practice sites must be strengthened and brought up to standard before training can begin.

## Challenges of Active Management of the Third Stage of Labor in a Peripheral Hospital

Dr. Kusum Thapa, obstetrician and gynecologist at Koshi Zonal Hospital in Nepal, related her efforts and experience in introducing protocols for AMTSL in her hospital.

Before Dr. Thapa's interventions, the standard practice at Koshi Zonal Hospital was expectant management: clinicians waited for the gush of blood signifying separation of the placenta from the uterine wall, either allowed the placenta to deliver spontaneously or applied cord traction with pressure on the fundus, and then finally injected 0.5 mg of ergometrine intramuscularly as long as the patient was not hypertensive. Following her participation in the MNH Program regional expert

initiative, Dr. Thapa introduced the standard AMTSL protocol as described in the MCPC.

Context of Safe Motherhood in Nepal

- MMR: 539/100,000 (His Majesty's Government, Nepal, Nepal Family Health Survey 1996)
- Approximately 90% of births take place at home
- Only 13% are attended by a skilled provider
- Hemorrhage is the number one cause of maternal death at 46.3% (1998 MMR Study)
- 23% of cases died within 2 hours
- 53% died within6 hours

Dr. Thapa described the challenges of introducing AMTSL to a staff that included senior physicians who were not sensitized to the use of evidence to guide clinical practice. To change attitudes of doctors and staff, the new standards were discussed during ward rounds, copies of the *MCPC* were made available, and special training sessions were conducted over lunch and tea breaks. There were additional challenges in preparing and implementing training, as the maternity ward lacked suitable space and adequate funds for training, and maternity staff could not be released for external training due to staffing shortages. To overcome these constraints, training took place in Dr. Thapa's home and in time-conserving batches. Funds were obtained from local businesses to supplement Dr. Thapa's own expenditures.

Dr. Thapa explained that Nepal's national standard practice guidelines are outdated and have not been effectively disseminated. Thus, these guidelines could not be used at the hospital. Instead, Dr. Thapa led efforts to review and update hospital protocols and to develop relevant job aids. In the Koshi Zonal District Hospital, human resources are scarce, with only one nurse in the birthing room. To adapt to this environment, nurses are told to load the oxytocin into the syringe during the second stage when the baby's birth is imminent. However, delays in administering the drug can still occur if the newborn is asphyxiated and resuscitation is required. Occasionally, nurses have omitted palpating the abdomen and, in two cases, administered the oxytocin prior to a second twin being born—fortunately with no adverse effect in either case.

Early on, ensuring a ready supply of oxytocin presented difficulties. The hospital does not supply the drug, but requires patients to purchase oxytocin themselves. Adjacent shops often ran out of the drug. To tackle this problem, Dr. Thapa and her colleagues visited all shopkeepers and asked them to increase their stocks, which they readily agreed to do. In addition, they enjoined the hospital's administration to purchase an emergency stock of oxytocin to prevent drug stock outs.

**Table 3** shows hospital statistics before and after the institution of AMTSL.

Table 3. Incidence of Postpartum Hemorrhage and Retained Placenta at Koshi Zonal Hospital before and after the Introduction of AMTSL

	RESULTS BEFORE AMTSL INTRODUCED (Sept. 2000–Aug. 2001)	RESULTS AFTER AMTSL INTRODUCED (Sept. 2001–Aug. 2002)
Total Births	3,539	4,036
PPH	48	11
Retained Placenta	12	2

"For us at Koshi Zonal Hospital, the tipping point came when the doctors realized that they were not being called in the middle of the night as often after the introduction of active management of the third stage. Then, they all became strong supporters and wanted all the nurses trained." Dr. Kusum Thapa, Koshi

Zonal Hospital, Nepal

Dr. Thapa concluded that AMTSL is a relatively simple, inexpensive, and effective intervention to prevent PPH. In her experience, the AMTSL clinical skills are easy to teach and implement. Nurses and midwives can quickly adopt the new technique and need only supervision during the early period after introduction as they perfect their skills. She noted that her physician colleagues quickly saw the advantages of the practice when there was a dramatic reduction in the incidence of PPH and retained placenta. In addition, the reduction in blood loss and in complications resulting from the use of AMTSL saves scarce hospital resources.

#### **USAID** Initiative on Prevention of PPH: Addressing Policy, Logistics, and Programming

Ms. Mary Ellen Stanton, Senior Reproductive Health Advisor at the USAID/W Bureau for Global Health, relayed information about the USAID initiative to prevent PPH.

This initiative has three components:

- **Country programming.** With support to a PPH prevention component to support existing maternal and newborn health programs in four countries: Benin, Ethiopia, Mali, and Zambia.
- Policy advocacy. A United States Pharmacopeia (Vol. 26, No. 5 Sept.—Oct. 2000 http://www.usp.org/standards/pf/2605/c00.html) study and work with the FIGO and ICM international professional societies.
- **Research.** Studies, such as on the use of Uniject<sup>TM</sup>, to deliver oxytocin or misoprostol in home births.

A key constraint to preventing PPH is that a large proportion of births occur at home, where skilled care and uterotonics are not available. Before relating the specifics of country programs, Ms. Stanton described other important issues that programs must address:

- Making the case to policymakers and clinicians: As Drs. Festin and Thapa mentioned, clinicians use a great variety of third stage management practices and rarely modify their approach on their own. Policymakers can seek to establish and enforce internationally accepted evidence-based standards, but must be educated about the latest evidence.
- Standards in the identification of uterotonics: There remains a lack of consensus on the types of uterotonics that are most suitable to lowresource and peripheral settings. Ergometrine, including oral formulations, is still routinely used.
- Registration of uterotonics/essential drug lists: To ensure wide availability, national programs should be encouraged to address drug registration issues. In the context of increasing decentralization and

- devolution of procurement, it is even more important for countries to include oxytocin and misoprostol on their essential drug lists.
- Distribution and storage: As described by Dr. Mathai, oxytocin is vulnerable to heat during distribution and storage. Cold chain management is required and presents challenges. Discussions with UNICEF on protocols for cold chain management of vaccines have highlighted the complexities of supplying non-vaccine drugs to the same facilities. A simple solution remains elusive, because vaccines are required to be stored separately.
- Mandate for providers: Who are the frontline providers and can they
  effectively perform active management of the third stage? Many
  countries still do not allow frontline providers, such as nurses and
  midwives, to administer injections, precluding them from performing
  what could be life-saving measures during pregnancy and childbirth.
- Planning for scale-up: Programs must decide how to ensure scale-up and whether to phase interventions.
- Planning for sustainability: The costs and requirement of ensuring continued implementation after the end of program support must be calculated and alternative sources of funds identified.
- Financing: Who covers what proportion of costs, and related questions, are important to program managers and policymakers and are key to addressing the issue of sustainability.
- Monitoring: The challenges of monitoring include the frequent paucity of data included in client records and delivery registers. These often need to be modified before useful information on PPH can be extracted. In addition, as described earlier, there are challenges to the measurement or estimation of blood loss. A focused program intervention may find an increase in PPH as a result of improved blood measurement or recording. Indicators can thus be a double-edge sword to advocates of PPH prevention and must be handled carefully. At the same time, improved measurement should be a required part of any program.

Ms. Stanton briefly described a multi-country initiative in Africa designed to strengthen PPH prevention as a part of maternal and newborn health programs. Lessons learned from these targeted programs include the following:

- Focus on PPH prevention resonates with policymakers and providers—it gets attention, energizes stakeholders, and gets action (nevertheless, there may be resistance and some people may need to be convinced).
- There are great variations in the way providers practice, even when updated standards of care are available.

"We have the opportunity to accelerate success in reduction of maternal mortality by putting the spotlight on postpartum hemorrhage—the biggest maternal killer.

Ms. Mary Ellen Stanton, USAID

- Letters/memos from the MOH supportive of new PPH prevention policies are very helpful.
- Cold chain solutions differ by country.
- Training to competency is shorter if the established norm includes some form of active rather than physiologic management of the third stage of labor; training models vary depending on existing local practices.
- Flexible, non-dogmatic approaches are essential for upgrading clinical care.
- With scarce financial resources, it is important to link new clinical training initiatives with existing systems and resources.

#### Joint FIGO/ICM Statement on Prevention of PPH

As a result of extensive advocacy by USAID and the MNH Program, FIGO and ICM issued a joint statement concerning the management of the third stage of labor to prevent PPH, and launched a Global Initiative on PPH in November 2003 during their conference in Chile.

Professor Walfrido Sumpaico, representing the Asia & Oceania Federation of Obstetrics & Gynaecology (AOFOG) and Ms. Asmuyeni Muchtar, representing the Indonesian Midwives Association, jointly presented the key messages of the joint statement and the commitments their organizations have made toward implementing the Global Initiative.

The Joint Statement recognizes the FIGO and ICM shared commitment to promote health, human rights, and well-being of all women, especially those at greatest risk of death and disability during childbearing. The purpose of the statement and the global initiative is to galvanize national professional associations to take action in favor of active management of the third stage. As relayed by Prof. Sumpaico, some of the key points of the joint statement are:

- Severe bleeding is the single most important cause of maternal death worldwide, and the majority of its victims die within 24 hours after childbirth.
- Every pregnant woman is at risk of life-threatening blood loss.
- Women with anemia are particularly vulnerable because they can tolerate less blood loss.
- Every woman must be closely observed and, if needed, stabilized during the immediate postpartum period.
- Active management of labor has been proven to decrease the:
  - incidence of PPH,
  - quantity of blood loss, and
  - need for blood transfusions.

- The components of active management are:
  - administration of uterotonic agents,
  - controlled cord traction, and
  - uterine massage after the delivery of the placenta, as appropriate.
- Every attendant at birth needs to have:
  - the knowledge, skills, and critical judgment to carry out AMTSL,
     and
  - access to needed supplies and equipment.

The full Joint Statement and Call to Action is presented in **Appendix C**.

As part of the Global Initiative, FIGO and ICM have committed to investigating promising new drugs and technologies for preventing and managing PPH. These may include the use of misoprostol, a uterotonic prostaglandin, and balloon tamponade, which is the use of an inflated condom to stop uterine bleeding and avoid uterine artery ligation and/or embolization.

Dr. Sumpaico added that national health professional associations have an important and collaborative role in advocacy, information dissemination, public education, and propagation of the concept of active management of labor.

Ms. Muchtar took the podium next and presented the FIGO/ICM Global Initiative and the commitment to disseminate and secure support for the PPH prevention initiative from UN agencies and international and national organizations.

She recommended that this Global Initiative for the Prevention of Postpartum Hemorrhage be integrated into the curricula of medical, midwifery, and nursing schools. In addition, FIGO and ICM will strive to ensure that:

- Every mother giving birth anywhere in the world will be offered AMTSL for the prevention of PPH.
- Every skilled attendant will have training in AMTSL and techniques for the treatment of PPH.
- Every health facility where births take place will have adequate supplies of uterotonic drugs, equipment, and protocols for both the prevention and treatment of PPH.
- Blood transfusion facilities will be available in centers that provide comprehensive healthcare (secondary and tertiary levels of care).
- Physicians will be trained in simple conservative techniques such as compression sutures and devascularization.
- Promising new drugs and technologies for the prevention and treatment of PPH, such as the tamponade technique, will be evaluated.

"I personally commit to take up the cause of the Call to Action at the next AOCOG [Asia-Oceania Congress of Obstetrics & Gynaecology] meeting in Chennai, India, later this year."

Dr. Walfrido Sumpaico, AOFOG

Ms. Muchtar added that the Indonesian Midwives Association has already taken up the challenge and is working toward implementing the elements of the joint statement through advocacy and practical clinical programs, such as sponsoring daughters of TBAs to attend midwifery school.

#### PREVENTING POSTPARTUM HEMORRHAGE IN HOME BIRTHS

## Effectiveness of Misoprostol for Prevention of PPH: Review of the Current Evidence

On behalf of the WHO, Professor Pisake Lumbiganon, of the Department of Obstetrics and Gynaecology at Khon Kaen University in Thailand, presented the results of a large multicenter WHO randomized trial of misoprostol in the management of the third stage of labor (Gülmezoglu et al. 2001).

This trial compared the use of  $600~\mu g$  of misoprostol with injectable 10~ IU oxytocin. Before the large multicenter trial was conducted, a pilot double blind, randomized misoprostol dose finding trial had been carried out in Thailand and South Africa (Lumbiganon et al. 1999). The pilot trial found that  $600~\mu g$  given orally was an appropriate dose for the larger study.

The WHO study was a randomized clinical trial, with double blind placebo implemented in nine study centers in nine countries<sup>5</sup>. With the exception of administering placebos either for the injection of uterotonics or for the oral misoprostol, routine practice was not modified significantly for the purpose of the study. During the period of the trial, all women admitted to the labor ward in each center were eligible. Excluded were women with asthma, severe chronic allergic conditions, planned cesarean section, and fever (>38°C), and those who refused to participate in the study. Investigators used 90% power to determine sample size, with a presumed 35% higher risk of excessive blood loss (>1000 ml) with one arm against the other. To power this hypothesis, approximately 20,000 women needed to be enrolled. The final study sample was 18,530 women out of 29,250 women screened. Between randomization and childbirth, 37 out of 9,264 women in the misoprostol arm and 32 out of 9,266 women in the oxytocin arm were taken for an emergency cesarean section and excluded from the study. Another 15 and 8 women respectively were excluded for missing data.

For this double blind, randomized clinical drug trial, the random allocation schedules were generated in Geneva and treatment packs were numbered consecutively following this schedule. Treatment packs were sealed to hide the contents of the pack. Each pack contained three tablets (misoprostol or placebo), one ampoule (oxytocin or placebo), one syringe, and swabs. Each woman received three tablets and an injection.

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<sup>&</sup>lt;sup>5</sup> The countries were: Argentina, China, Egypt, Ireland, Nigeria, South Africa, Switzerland, Thailand, and Vietnam.

Women were randomized during the second stage of labor when a vaginal delivery was expected.

Primary outcomes measured were: 1) measured blood loss >1000 ml, and 2) frequency of additional uterotonic administered due to excessive bleeding. Data on secondary outcomes were also collected, including: 1) measured blood loss >500 ml, 2) blood transfusion, 3) manual removal of the placenta, 4) late hemorrhage (after the first hour), and 5) treatments for severe hemorrhage requiring hysterectomy or bimanual compression. The WHO protocol for the measurement of blood loss for the outcome measures was to:

- Start immediately after the cord was cut.
- Change dirty linen and receivers.
- Collect all blood, clots, and swabs soaked with blood, using a flat bedpan or bucket.
- Transfer all of the contents to the measuring jar provided, and measure.

Because misoprostol was known to cause side effects, data were also collected on the incidences of shivering, vomiting, diarrhea, fever (>38°C), changes in blood pressure, and any other adverse/serious adverse event (WHO/GCP 1995).

The characteristics of the women in each arm of the study were roughly the same. The study found that 380 out of 9,214 women (4%) in the misoprostol arm and 263 out of 9,228 women (2.9%) in the oxytocin arm of the study experienced more than 1,000 ml of blood loss. For the use of additional uterotonics, the results were 1,398 out of 9,225 (15.2%) versus 1,002 out of 9,228 (10.9%) women respectively. Relative risk data are reported in **Table 4**.

Table 4. Primary Outcomes and Numbers Needed to Treat from WHO Multicenter Trial of Misoprostol versus Oxytocin for the Management of the Third Stage of Labor

	MISOPROSTOL N= 9,225 %	OXYTOCIN N = 9,228 %	RELATIVE RISK (RR)	95% CI (RR)	NUMBER NEEDED TO TREAT (NTT)	95% CI (NTT)
Blood Loss >1000 ml	4.0	2.9	1.39	1.19–1.63	89	61–167
Additional Uterotonics	15.2	10.9	1.40	1.29–1.51	23	30–57

Source: Gülmezoglu et al. 2001.

Blood loss of more than 500 ml showed a similar relative risk, but interestingly, blood transfusions were less likely in the misoprostol arm although the difference was not significant. There were no other significant differences in other secondary outcomes. As expected, side effects were more common in the misoprostol group, particularly for shivering and fever, although shivering disappeared within 2–6 hours of

childbirth. Fever and diarrhea gradually dissipated over 12–18 hours. (Note: Only two sites collected data on side effects beyond 1 hour.) For every eight women treated with misoprostol, one additional woman will have "shivering," and for every 19, one will have fever.

Professor Lumbiganon then reviewed the pharmacokinetic properties of the two drugs involved in the study.

Oxytocin has a more rapid peak than does misoprostol according to blood plasma analysis, peaking within minutes of administration. Misoprostol does not peak until 30 minutes, but is detectable in blood plasma almost immediately and rises quickly.

Professor Lumbiganon also discussed the results of a systematic review of randomized controlled trials involving misoprostol to prevent PPH (Villar et al. 2002). Sixteen trials were included in the final review, among which 10 compared misoprostol (600 µg, 500 µg, or 400 µg) to various uterotonics, while the remaining trials compared misoprostol to a placebo. All but the WHO trial discussed above were relatively small and underpowered trials. In the illustration presented, however, the subtotal of combined results of all the trials comparing misoprostol 600 µg to injectable uterotonics was the following: 380 out 10,539 (3.6%) women receiving misoprostol versus 280 out of 10,560 (2.7%) for the injectable uterotonic group suffered blood loss in excess of 1,000 ml for a relative risk of 1.36 (95% CI 1.17–58). In any case, the authors of the paper concluded that oxytocin was superior to misoprostol for the management of the third stage of labor where there is a skilled provider. For his part, Professor Lumbiganon concluded that 10 IU oxytocin, either IM or IV, should be the norm where active management is practiced; however, misoprostol may also be effective in the treatment of PPH.

Dr. Sanghvi followed with a discussion of the implications of these results.

Before the effectiveness of misoprostol was under consideration, a safe, effective, and scalable intervention already existed to prevent PPH: AMTSL using oxytocin. For facility-based births, there is no need to deviate from the standard protocol for active management. The potential usefulness of misoprostol is for prevention of PPH in home births, not hospital births. In Asia, more than 50% of births occur at home and, with a few exceptions, no country has been able to take skilled care to all home births. The best current estimates indicate that it will take approximately 25 years for all births in the region to be attended by a skilled provider. As described earlier, the logistics of maintaining a cold chain to reach the most peripheral populations are daunting. On the other hand, the following characteristics of misoprostol make it suitable for use in preventing PPH at home births:

- It is not heat- or light-sensitive.
- It is relatively inexpensive.

"Do not let the best be the enemy of the good." Dr. Harshad Sanghvi,

JHPIEGO, after François

Voltaire, 1694-1778

It is taken orally.

- It offers rapid action by oral, vaginal, buccal, and rectal routes.
- Its side effects are predictable and self-limiting.

The WHO trial did not include assessments of whether the side effects were acceptable to women when the women have been properly counseled to anticipate these effects.

As Goldberg, Greenberg, and Darney (2001) noted, there is good and consistent evidence to support the recommendation (category A recommendation) to give 400–600 µg of misoprostol orally or rectally after the birth of the baby but before delivery of the placenta for prevention of PPH, when other uterotonic agents including oxytocin and ergometrine are not available.

Table 5. Comparison of Blood Loss in Excess of 1,000 ml with Misoprostol versus Oxytocin

	MISOPROSTOL	OXYTOCIN
Blood Loss >1000 ml	366/9,214 (4%)	263/9,228 (3%)

Source: Gülmezoglu et al. 2001.

**Table 5** above, taken from the WHO multicenter study, demonstrates that although oxytocin is slightly more effective than misoprostol, the latter is still remarkably effective in reducing PPH. Using no uterotonic may result in a much higher incidence of hemorrhage (almost 17% for physiologic management).

In applying these findings to practice, several concerns will likely emerge. One is the issue of selecting the right frontline worker to distribute the drug. Because safe motherhood goals and current best practices dictate the promotion of skilled care at birth, "empowering" TBAs with this drug may not be in keeping with the global agenda. Ultimately, countries must weigh their options in how to deliver this potentially life-saving medication to women and make the decisions that fit their situation. Additional worries about the potential misuse, or the mistiming of use, of misoprostol must also be addressed.

In response to questions suggesting the need for additional research on the effectiveness of misoprostol in the management of the third stage, Dr. Sanghvi noted that the important research questions are not whether misoprostol is equally effective as oxytocin, but whether it is better than nothing, and what are the implications of increasing uterotonic coverage for home births. He concluded that misoprostol offers a suitable solution for preventing PPH at home births.

## Oxytocin in Uniject™ Devices: Current Evidence and Research in Progress

Dr. Vivien Tsu, Senior Program Advisor of the Program for Appropriate Technology in Health (PATH), presented another alternative for AMTSL in home births: the use of a pre-filled, single-use disposable device for injecting oxytocin, called Uniject<sup>TM</sup>.

Uniject has been used to deliver other injectable drugs, including tetanus toxoid in Bolivia, Indonesia, Mali, and elsewhere; Cyclofem, a combined hormonal contraceptive, in Mexico; and hepatitis B vaccine in India and Indonesia. Its use for delivering oxytocin has been studied in Angola and Indonesia. The advantages of the Uniject device are that it ensures safe injection practices, including preventing re-use of syringes and needles a common practice in Asia—and is easy to use. Sterility is more easily maintained, as is dose accuracy. Providers can be trained in only 1–2 hours by giving two or three practice shots, and they are generally overwhelmingly enthusiastic about the device. The Indonesia study sought to determine whether community midwives could safely use the device in home births. Safety was established; in addition, midwives reported preferring the device to standard syringes and needles and attested that they would be willing to pay a marginal cost increase if it were commercially available. In response to questions about cost that emanated from the plenary discussion, Dr. Tsu reported that, although the device has not yet been prepared for commercial manufacture, indications suggest that prices will be slightly higher than the standard ampoules with traditional syringes and needles.

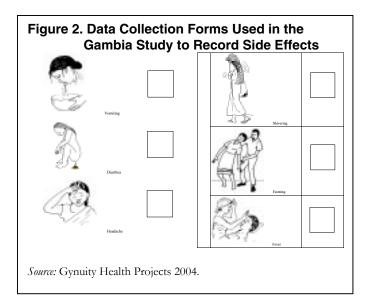
Dr. Staffan Bergstrom, a conference participant from the Karolinska Institute, Sweden, offered copies of a short presentation on the Angola Uniject study, for which he is the principal investigator.

The study compared the use of Uniject with 10 IU oxytocin, early cord clamping, and CCT with physiologic management of the third stage. In addition to reducing PPH from 40.4% to 8.2%, Uniject was found to be well tolerated by parturient women in this study.

## Preventing PPH in Home Births: Some Lessons from an Ongoing Study in a Rural, Home Birth Setting

Ms. Jennifer Blum, Staff Program Associate at Gynuity Health Projects and the Population Council, described the preparation and early implementation for an ongoing trial of misoprostol for use in the management of third stage of labor and administered by TBAs in the Gambia, West Africa.

Ms. Blum was presenting on behalf of a research team consisting of Dr. Gijs Walraven, Principal Investigator, and staff at the Medical Research Council, Gynuity Health Projects, and the Population Council. This randomized, double blind trial compares misoprostol 600 µg to the use of oral ergometrine 2 mg, which is currently routinely used by TBAs. Ms. Blum described the challenges of conducting research with non-literate TBAs. In the study, TBAs collect blood after childbirth. The blood is measured and weighed by trained community health nurse-midwives. For information about the incidence of side effects, study investigators have designed forms with pictographs (see **Figure 2**). TBAs were trained to recognize these side effects using matching pictorial aids.



## Moving Misoprostol Out: Registration, Availability, and Distribution

Dr. Beverly Winikoff, President of Gynuity Health Projects, provided a technical overview of pharmaceutical regulatory processes in the context of misoprostol.

As an introduction to discussing drug regulatory procedures, Dr. Winikoff provided an overview of misoprostol and its potential as a reproductive health product. In countries where misoprostol is available, it is almost always approved only for the prevention and treatment of gastric ulcers associated with the use of non-steroidal anti-inflammatory drugs (NSAIDs). It also causes contractions of smooth muscles of the uterus, which in turn reduces bleeding, opens the cervix, and empties the uterus. Thus, misoprostol has many potentially important reproductive health uses, including:

- Treatment of incomplete abortion
- Treatment of intrauterine fetal death
- Induction of labor
- Softening of the cervix for gynecologic procedures
- Prevention of PPH
- Treatment of PPH

Misoprostol has other advantages in that it is relatively inexpensive, easy to transport and store, easy to administer, and safe.

The following terms are relevant to drug regulation:

• Drug registration (or authorization or licensing): authorization by a government for a particular company to market (sell) a particular formulation of a drug for a particular purpose. This is a commercial act, intended to protect the public and ensure drug safety. A

- government that wants to supply a drug in the public sector does not necessarily have to register it.
- Registered (or authorized or licensed) indication: purpose for which the authorized drug may be marketed. The safety and efficacy of the drug for this indication must be proven scientifically to the satisfaction of the drug regulatory agency. A pharmaceutical company, which is the authorized marketer, may add a new indication to its file if it produces scientific evidence validating the safety and efficacy of the new use to the satisfaction of the regulatory agency.
- Patented drug: a drug whose production and marketing is reserved for the "patent holder." No other entity can market that compound for the life of the patent.
- Generic drug: a compound biologically equivalent to an originally patented drug and registered for the same indication and in the same dose as the original drug.
- Regulatory file: the entire dossier of information on which regulatory bodies base their market authorizations (registrations). The file contains:
  - Information about the compound, including chemistry, pharmacology, and animal and human toxicity
  - Specifications about the manufacturing process
  - Scientific data meeting regulatory standards proving the drug is safe and effective for its proposed indications
  - Instructions for the use of the drug

A company cannot market a drug it owns for an indication that is not registered. This means that it cannot advertise or provide brochures or educational information on unauthorized indications. Use of drugs for unregistered indications ("off-label" use) may not be reimbursable in certain insurance schemes, may not be permitted in some government-run health services, and may pose risks in certain environments.

Only a generic (same drug/same formulation and dosage/same indication) does not require a complete regulatory file. A new indication can be registered by the original file holder or by an entity with a complete new file. If the original marketer does not want to add an indication, the task of registering an equivalent drug for a new indication is daunting. The best circumstance for availability, accessibility, and safe use of a drug is when a product is registered for its indication, marketed and promoted for that indication, and available through normal commercial and subsidized channels.

Currently, misoprostol is available in many, but not necessarily all, countries. It is lacking registration in African countries in particular (see **Figure 3**). Nowhere has it been registered for an indication for the prevention of PPH, although it is registered for other reproductive health indications in Brazil, France, and Egypt.

Whether or not it is registered, misoprostol is widely available. Physicians routinely use it off label, which is legal in most countries. In countries where it is not registered or available through official commercial channels, clinicians can access the drug through informal commercial channels from other countries (governments may unofficially support these strategies).

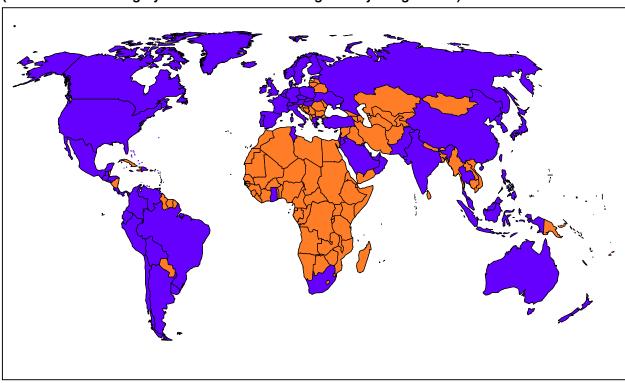


Figure 3. Countries Where Misoprostol Is Registered (Countries in darker grey are those where the drug is not yet registered.)

Source: Gynuity Health Projects 2004.

Dr. Winikoff enjoined the conference participants to make availability and accessibility of misoprostol an issue. She encouraged advocacy groups, including professional associations, to disseminate information about misoprostol use and to apply pressure to put uterotonic drugs on national and international essential drug lists. Gynuity Health Projects is also exploring creative public-private partnerships with small companies willing to take risks. These companies may enter into agreements with governments to register the drug if it can be made available for a reduced price. All champions of PPH prevention should seek help from governments in supporting registration and commercialization of misoprostol and other uterotonics.

# PREVENTING POSTPARTUM HEMORRHAGE IN HOME BIRTHS: THE INDONESIA EXPERIENCE

# Results from a PPH Prevention Project in Indonesia

The project team<sup>6</sup> took turns discussing the implementation process and results of a demonstration study in rural West Java, Indonesia, to prevent PPH among women living in areas where a high proportion of births are not attended by skilled providers.

The purpose of the study was to demonstrate the Safety, Acceptability, Feasibility, and Program Effectiveness (SAFE) of community-based distribution of misoprostol for prevention of PPH in rural Indonesia.

Between 4.5 and 5 million women give birth in Indonesia each year. Approximately 18,000 of them die as a result of pregnancy and childbirth. At the time the study was designed, data showed that almost half of these deaths were due to PPH, which can lead to death within 2 hours if it is not managed immediately. More recent data (Indonesia Demographic and Health Survey 2003) indicate that skilled providers attend 60% of births, and that for 7% of births, women reported "excessive bleeding."

The study took place within the context of the existing health system in West Java, which advocates for skilled providers at every birth. In this area, community midwives were trained to practice AMTSL. Various programs have offered training to midwives in life-saving skills and/or basic emergency obstetric care, which include the management of PPH. In addition, West Java benefited from behavior change and social mobilization efforts to increase birth preparedness and complication readiness. The central message of birth preparedness is the advantage of giving birth with a midwife or other skilled provider in attendance.

Before data collection began, an extensive infrastructure was put in place to coordinate and monitor the project. This included a National Steering Committee, made up of various stakeholders including the Indonesian Society for Obstetrics and Gynecology, which was responsible for organizing the required ethical reviews and obtaining MOH approvals at national, provincial, and district levels. In addition, there were extensive stakeholder discussions and consultations as the study was being proposed and designed. Providers, both physicians and midwives, women's groups, community and informal leaders, including community health volunteers or *kaders*, as well as government officials participated in these discussions.

The Prevention of Postpartum Hemorrhage Study offered a preventive health intervention, including a dose of misoprostol taken immediately

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<sup>&</sup>lt;sup>6</sup> The team was composed of: Professor Dr. Gulardi Wijnjosastro, obstetrician/gynecologist and Indonesia Principal Investigator; Dr. Mohammad Zulkarnain, MMedSc, Field Epidemiologist; Dr. Gail Fraser Chanpong, DrPH, Epidemiologist and Study Manager; and Dr. Harshad Sanghvi, MD, JHPIEGO Principal Investigator.

after the birth of the baby, which was designed to lower the incidence of PPH at unattended home births. The health intervention included sharing information about preventing PPH in both study and comparison areas, with the distribution of misoprostol among pregnant women only in the intervention area. Counseling was offered as soon as the trained community volunteer (*kader*) identified a pregnant woman. The *kader* then distributed misoprostol later in the pregnancy, around the eighth month, along with a second round of counseling.

The intervention area included seven villages in the *kabupaten* or regency of Bandung; the comparison area consisted of 11 villages in Subang regency. Although both districts are primarily rural and economically depressed, with a history of high maternal mortality, the proportion of births attended by midwives was significantly higher in Subang.

Trained community volunteers made home visits to pregnant women and recruited them into the study. Verbal informed consent ensured that women could refuse participation in the study and yet still benefit from the intervention, which included counseling about the risks and danger

signs of PPH as well as access to free medical care in cases of a referral. The role of the midwife and her ability to administer drugs that can prevent PPH were highlighted as part of the counseling. In the intervention area. volunteers offered additional information about the timing and safe use of misoprostol and the risks associated with taking the tablets too soon. The side effects of misoprostol were described, as well as steps to take to alleviate

Figure 4. Illustration Included on Safety Reminder Card and Misoprostol Pill Packet

Source: JHPIEGO 2002.

these effects. The pre-packaged packets of misoprostol also included a safety reminder card (see **Figure 4** for the illustration included on the card).

During and after the intervention, the field study team conducted interviews to collect information on the safety, acceptability, and feasibility of taking the drug. An obstetrician investigated any adverse events (in which a woman experienced a serious complication during childbirth). In addition, in-depth interviews were conducted among husbands, support persons, *kaders*, community midwives, and TBAs.

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<sup>&</sup>quot;They seemed to accept it.... The women are grateful because they are afraid of bleeding. But with this Tablet PAS program, they become more at ease."

<sup>&</sup>quot;She was bleeding when she delivered her first baby, but the second one, she participated in this program, got the medicine, so [there was] no bleeding."

Traditional Birth Attendant

Data collected on attendance at birth are shown in **Table 6**. Concerns that providing a preventive drug might lead to reduced reliance on midwives were proved unfounded. Data on the place of birth (not shown) demonstrated that women in the intervention areas were more likely to have given birth in a facility during the index birth as compared to a previous birth.

Table 6. Coverage of Uterotonic Agents at Births in Intervention versus Comparison Areas

USE OF UTEROTONIC AGENTS	INTERVENTION AREA  (n=1,282*) (55% were attended by skilled health provider)  %	COMPARISON AREA  (n=475**)  (74% were attended by skilled health provider)  %
Some Uterotonic	93.7 (injection or misoprostol)	76.8 (injection)
No Uterotonic	5.9	22.8
Not Sure	0.5	0.4

<sup>\*</sup> Excludes 40 C-sections

The PPH study in Indonesia established the safety of home-based community distribution of misoprostol. Study participants were able to repeat safety information after receiving counseling from trained community volunteers. Women understood that they should seek care if excessive bleeding occurred with or without use of the intervention drug. None of the study participants who used misoprostol required referral for additional care because of increased symptoms or side effects following childbirth.

Women who took misoprostol did experience the expected side effects as compared with women in the comparison area (see **Table 7**).

Table 7. Prevalence of Side Effects at Birth in Intervention Area versus Comparison Area: Indonesia PPH Study

SIDE EFFECT	INTERVENTION* AREA (%)	COMPARISON AREA (%)	p VALUE
Shivering	38.9	9.5	p<0.001
Fever	28.9	5.1	p<0.001
Cramping	28.4	9.9	p<0.001
Nausea	12.4	2.1	p<0.001
Vomiting	4.4	0.0	N/A

<sup>\*</sup> PPH study protocol called for an intent-to-treat based comparison.

The demonstration study concluded that the intervention was acceptable. Trained and supervised *kader* successfully provided counseling and information on prevention of PPH, and then safely distributed misoprostol. Women understood the information provided by the *kader*,

<sup>\*\*</sup> Excludes 14 C-sections

acted on it, and safely took misoprostol at the correct time. Women were adequately prepared to cope with increased minor discomforts that were predictable after use of misoprostol.

Interview results indicated that:

- 88.4% would recommend the misoprostol tablets to a friend
- 79.5% would use it in the next pregnancy
- 78.1% would be willing to purchase it if it were not available free
- Among those willing to purchase medication, 60% reported being willing to pay at least Rp. 5000 (or approximately \$0.50 USD)

The study used several measures of program effectiveness. Coverage of uterotonics—oxytocin or misoprostol—was significantly higher in the intervention area (93.7%) than the comparison area (76.8%). The overall number of emergency referrals due to birth complications was less than 10% (176/1,811), with only 47 emergency referrals suspected to be PPH. Emergency referrals due to suspected PPH, which in home births may reflect a perception of excessive bleeding and a willingness to act upon it rather than a clinical diagnosis, included 2.1% (28/1,322) of the overall emergency referrals in Bandung, compared to 3.9% (19/489) of referrals in Subang. Significantly fewer women in the Bandung intervention area had emergency referrals for any birth complication, including PPH (Chi²=6.6919, p=0.010).

A logistic regression model to adjust for differences in age, parity, education, economic status, and antepartum hemorrhage history between study areas showed that women in the intervention area, when compared to the comparison area, were:

- 25% less likely to perceive excessive bleeding (OR 0.76 [95% CI 0.55–1.05])
- 30% less likely to need an emergency referral to a health facility (OR 0.69 [95% CI 0.49–0.98])
- 45% less likely to need an emergency referral for PPH (OR 0.53 [95% CI 0.24–1.12])

The study team concluded that the safety, feasibility, and acceptability of home-based distribution of misoprostol were sufficiently established by the Prevention of Postpartum Hemorrhage Study results. Women were aware that the medication might result in some short-duration side effects and knew what to do if side effects occurred. Most participants and their families had favorable comments about the counseling intervention and drug use to prevent PPH, and a large proportion of users are willing to take misoprostol in the next pregnancy, recommend it to a friend, and pay for it. The combination of the use of active management of third stage using oxytocin provided by a midwife and the use of misoprostol by the woman herself if a midwife is not available has the greatest potential for expanding prevention of PPH.

The PPH study team recommended that a step-wise approach be used to scale up and roll out the prevention of PPH intervention. In planning the scale-up, policies regarding drug distribution by community volunteers need to be addressed.

# Action Plan for Implementing Large-Scale PPH Prevention Programs in Indonesia

Dr. Ieke Irdjiati Syahbuddin, Secretary to the Director General of Public Health, whose role is to coordinate, plan, and budget public health programs, was charged with presenting the response of the MOH to the PPH demonstration project in West Java.

Dr. Syahbuddin's presentation began with a reminder of the daunting task that scaling up an intervention presents in Indonesia. The country has a population of 204 million scattered over 17,508 islands, although 59% of the people live on the islands of Java and Bali. Administratively, the country is divided into 30 provinces, 343 districts (composed of municipalities and regencies or kabupaten) and 64,367 villages.

Over the past two decades, the Indonesian government has devoted considerable efforts to address maternal mortality. Data from demographic and health surveys (DHS) in 1994, 1997, and 2003 show a gradual decline from 390/100,000 live births to 344 and 307 respectively. In the latest DHS, 66% of births are attended by a skilled provider, although for the province of West Java the proportion is lower—47%. A separate household survey (Indonesia Ministry of Health 2001) estimates that hemorrhage accounts for 28% of maternal deaths and is still the main cause of maternal death. Indonesia has been an active implementer of the WHO Making Pregnancy Safer (MPS) initiative and also has developed its own strategy, which states that:

- All pregnant women and their newborns should be able to access skilled care during pregnancy, childbirth, and the postpartum period.
- All women and their newborns should be able to access referral care when complications arise.
- Every woman of reproductive age should have access to prevention and management of unwanted pregnancy and complications of unsafe abortion.

Within the context of the MPS strategy, the MOH has sought to improve both the prevention and management of PPH. Management of PPH is incorporated into various nationally recognized and approved training curricula. In addition, health promotion efforts, such as birth preparedness/complication readiness campaigns, address the potential risks of PPH and danger signs that families and communities should recognize. In the context of prevention, the MOH seeks to expand the use of active management of the third stage, including the use of injectable oxytocin by skilled providers. Guidelines and standards already

## Indonesia's Recommendations to Other Countries on Use of Misoprostol

- It is suitable for countries or regions where a large proportion of births are not attended by skilled providers.
- It is suitable for areas with an existing network of community workers or volunteers who are willing to visit all pregnant women.
- Commitment at the national level to scale up must be obtained, if introduction of the intervention is successful in a small area.
- Sufficient investment in training and supervision must be made.
- Progress and drug distribution must be monitored.
- Training and counseling materials, program implementation guides, evaluation tools, and posters will be available from the MNH Program in 2004.

exist and have been disseminated. The MOH is studying the possibility of scaling up the use of Uniject<sup>TM</sup> for community midwives and peripheral providers as a means of increasing access to uterotonic drugs. In addition, the MOH supports a step-wise expansion of misoprostol distribution for home births that are not attended by a skilled attendant. This official support came about through the intervention of the National Steering Committee for the misoprostol PPH study, which included the Director General of Public Health. At the conclusion of the study, the Committee met and determined to take the following steps:

- recognize that PPH is still a major preventable cause of maternal mortality in Indonesia,
- present key findings of the PPH study to the Minister of Health,
- recommend an expansion of the PPH preventive health strategy,
- disseminate the study results widely, and
- advocate for commitment from regional health authorities and donors.

As a result of the Committee's efforts, the Minister issued an official resolution on 18 July 2003 that called for incorporating the dual options for PPH prevention (AMTSL and community-based misoprostol) into the national health strategy. To carry this out, a key task involves ensuring the availability of misoprostol and its distribution to peripheral health facilities. The MOH is working to order the drug in bulk and repackage it for purposes of PPH prevention before entering it into the distribution system for the community health centers or puskesmas. The MOH and the MNH Program are also working to emphasize PPH prevention further in the birth preparedness campaign. In addition, the relevant units were instructed to prepare a budget for rolling out misoprostol to selected districts in five provinces as part of their planning for 2004. Dr. Syahbuddin reported that the MOH and the Indonesia Finance Minister renewed the government's commitment to scale up the Indonesian National PPH Program within targeted districts in five provinces with a new allocation of Government of Indonesia funds (Rupiah 500 million =  $\sim$  \$ 60,000 USD).

The MOH is currently implementing an action plan for wider implementation of misoprostol for PPH prevention. Results of the study are being disseminated to provincial and district governments. As part of the dissemination, the central MOH is emphasizing two key messages:

1) implementation must include training of health personnel with a special emphasis on how to counsel pregnant women, and 2) systems for strict monitoring of misoprostol supplies must be established, with the head midwife of community health centers held responsible and accountable. Local implementers have to develop their own locally adapted ways of identifying and contacting pregnant women, with the West Java experience of using community volunteers as an example. The central MOH also recommends strongly that documentation systems be established to monitor safe use of misoprostol. If misoprostol is given to women during pregnancy, counseling on safe use is essential.

After disseminating the model to local governments, the MOH will identify a few districts in different regions of the country in which to roll out the intervention. Expansion will be done incrementally from that district within its region. Specific line items of the budget are being prepared for socialization, preparation/adaptation of training materials and job aids, preparation of monitoring tools, and training of midwives and community volunteers as well as procurement and repackaging of misoprostol. Recently, the national-level budget was authorized and meetings have been conducted with West Java provincial and district officials who have developed a plan of action for that province. Drug procurement efforts have begun and are ongoing.

## ADDRESSING THE CHALLENGES FOR TREATING PPH

# **Emergency Obstetric Care for Postpartum Hemorrhage: The AMDD Experience**

Dr. Zafarullah Gill, Associate Director of the Averting Maternal Death and Disability (AMDD) Program at Columbia University, described experiences in improving access to emergency obstetric care (EmOC).

The 5-year, \$50 million AMDD Program began in 1999 with funding from the Bill and Melinda Gates Foundation. Its goal is to improve the availability, quality, and utilization of EmOC services. Its strategy is to work through project partners, such UNICEF, UNFPA, CARE, Save the Children, the Regional Prevention of Maternal Mortality (RPMM) Network, and the Reproductive Health Response in Conflict (RHRC) Consortium. In addition, AMDD has technical partners, such as JHPIEGO, Family Health International, EngenderHealth, the India Institute of Management, and John Snow, Inc.

The basic tenet of AMDD is that, once a woman is pregnant, complications cannot be predicted or prevented; therefore, all women need access to EmOC services. There are two types of life-saving measures for EmOC, depending on the level of facility where they can realistically be given. Thus, a basic EmOC facility will carry out the following functions:

- Provide parenteral antibiotics, oxytocics, and anti-convulsants
- Perform manual removal of placenta
- Perform the removal of retained products
- Conduct assisted vaginal deliveries

A comprehensive EmOC facility will offer surgical services, such as cesarean sections, and blood transfusions in addition to the same procedures as a basic EmOC facility.

The WHO has recognized the effectiveness of this approach and promoted these services. But a recent UNICEF assessment found that there are huge gaps in the availability of EmOC. To expand availability, AMDD recommends upgrading and strengthening services at existing facilities rather than creating new facilities. The inputs for doing so include many aspects, such as renovations, supplies and equipment, data records and monitoring, staff deployment and supervision, quality improvement processes, and the like. Dr. Gill highlighted one important aspect, which is training of staff. In Asia, AMDD has worked with JHPIEGO to develop a competency-based EmOC training package, which uses the WHO manual *Managing Complications in Pregnancy and Childbirth* as the reference. The set of materials includes a special package for anesthetists.

This training package was used for training a core team of providers from six countries in Asia. A hospital in Dhaka was strengthened and used as a training site for teams who attended a knowledge update, skills standardization workshop, and clinical training skills activity. The team—composed of physicians, midwives, and anesthetists—was trained as a group and has since trained other providers in their countries. The training package is being translated into French and Spanish to replicate EmOC competency-based training in Africa and Latin America and the Caribbean.

## **Innovative Treatment Approaches**

The current state of the art for managing PPH in low-resource settings includes performing manual removal of the placenta and bimanual compression of the uterus while administering uterotonics and fluids to treat shock. Should these procedures fail—and they typically do in 10% of PPH resulting from uterine atony—the provider can apply aortic compression while transferring the patient to surgery for a hysterectomy. (Hysterectomy can have devastating social consequences for a woman of reproductive age in a developing country.) Other long-term morbidity of PPH includes anemia, infertility, and, in some cases, Sheehan's syndrome.

Dr. Sayeba Akhter, Professor in the Department of Obstetrics and Gynecology at Dhaka Medical College, Bangladesh, presented a number of new techniques for the management of PPH.

The first, the B-Lynch brace technique, requires opening the abdomen to compress and then suture the uterus. A demonstration of this technique was carried out on an anatomic model during one of the skills laboratories at the conference.

The second technique described was balloon tamponade. Reports have been published about the use of the Sengstaken-Blackmore tube or Rusch urological hydrostatic balloon catheter to apply pressure on the fundus and compress the blood vessels (Guptha and Pande 2001; Johanson et al. 2001; Selo-Ojeme 2002). But these devices are expensive

"I have a friend whose mother died of post-partum hemorrhage giving birth to her. Every birthday, she cries because she remembers that she was the cause of her mother's death."

Dr Sayeba Akhter, Dhaka Medical College, Bangladesh and their mechanism is complex. Dr. Akhter has adapted this technique using a condom, a sterile catheter, and saline solution. The balloon, created from infusing saline solution through the catheter into a condom, which is then tied to the catheter and inserted in the uterus, applies hydrostatic pressure, which can be gradually increased until tamponade occurs. Once bleeding has stopped, the catheter is folded, tied, and held in place to maintain pressure. Dr Akhter recommends packing gauze to prevent the balloon from slipping out of the uterine cavity. In the meantime, uterine contractions are maintained with an infusion of oxytocin for 6–24 hours. The condom can be deflated 24–48 hours later and the patient given prophylactic antibiotics.

In her hospital, this technique has been used for the past 18 months with cases of primary and secondary PPH when medical and basic surgical approaches failed to control the hemorrhage. In that period, 30 patients were treated with condom tamponade. The amount of saline needed ranged from 245 to 425 ml. Bleeding was stopped in all patients within 15 minutes. On average, patients also needed three pints of blood. Dr. Akhter reported that no laparotomies have been conducted in her hospital since this technique was introduced.

Given the simplicity of the condom tamponade technique, it may be suitable for use by skilled providers in rural, peripheral settings. The Dhaka team has trained providers in a district hospital, where they are using it successfully. As a result, they no longer refer cases of intractable PPH, yet have not had any fatalities. Before it is expanded to lower-level facilities, Dr Akhter recommends a rigorous evaluation using a standard protocol. Such a study would require using several centers to garner sufficient caseloads.

# Getting Quality Emergency Care to Remote and Rural Communities

Dr. Jeffrey Smith, Associate Professor of Obstetrics and Gynecology at the Johns Hopkins School of Medicine and JHPIEGO Safe Motherhood Advisor for the USAID/REACH project in Afghanistan, reviewed options for providing emergency care for PPH in remote and rural areas.

Dr. Smith began by noting that childbirth with a skilled provider often lags behind coverage for antenatal care. The unscheduled nature of births makes it more difficult for women to access care. Yet access to skilled care is critical in case of a complication. While other complications, such as obstructed labor, eclampsia, or sepsis need attention within 12 to 48 hours, a woman suffering from severe hemorrhage may die within 2 to 6 hours.

Studies have been attempted to examine whether nipple stimulation could assist in inducing uterine contraction and limit hemorrhage. Results of a randomized clinical trial of 4,227 births found no difference between

the suckling and the control group (Bullough, Msuku, and Karonde 1989).

A study of the knowledge, attitudes, and practices of TBAs in the Gambia found that they understand the essential actions of the third stage, can recognize PPH, and can describe what is needed to address it. They will often start the referral process. However, they are not always present when the hemorrhage begins, but are called after the problem occurs (Bij de Vaate et al. 2002).

A large study conducted in Matlab in Bangladesh investigated the effect of placing trained midwives in villages. Results showed that midwives were able to treat or refer major complications, most commonly PPH and sepsis, and provide postabortion care. Data collected over 3 years demonstrated that women were 31% less likely to die of maternal causes in the period after the placement of midwives, as compared to the period prior (OR 95% CI 0.11–0.81) (Faveau et al. 1991).

Families and TBAs cannot be expected to perform the life-saving procedures at home. Difficulties in terrain and lack of resources for emergency transportation as well as delayed decision-making all contribute to maternal deaths in rural and remote areas. Therefore, both preventive and emergency care must be readily available nearby. To treat PPH, providers must be available, skilled in recognizing PPH, and able to give uterotonic drugs and apply clinical procedures (e.g., manual removal of the placenta, bimanual and aortic compression).

The MNH Program worked in Nepal to establish basic obstetric first aid in rural areas. Simple diagnostic and treatment protocols were developed. Maternal and child health (MCH) workers were trained and given a basic drug and supply kit. One lesson from the project was that MCH workers who are not involved in many births lose their skills. However, clinical supervision can enhance their performance. Also, it is difficult to maintain a focus on obstetric first aid rather than general health services. Recruitment of MCH workers from the local area is also vital to their effectiveness.

In Afghanistan, JHPIEGO is working to develop a new cadre of skilled provider: the community midwife. This fully trained midwife will be posted at the health center level and interact with the community to promote facility-based services. To complement her, community health workers will help identify pregnant women and arrange for a visit by the community midwife.

There are several challenges to ensuring that skilled providers attend births. First, they must have access to medication, which is continuously stocked and adequately stored. Second, there are concerns that the uterotonic drug may be misused or abused and given during labor, for example. Clinical procedures must be applied appropriately and with the correct technique. Providers in the health system must accept the role of the community caregiver. Finally, providers will not be effective unless

women and their families see them as a valuable resource and accept their care.

In conclusion, the best approach to managing PPH emergencies is **to be prepared**. All elements of the health system must be in place (Safe Motherhood Action Agenda 1998).

- **Policies** must promote the use of skilled attendants, birth preparedness/complication readiness (BP/CR), and appropriate access to uterotonic drugs.
- **Facilities** must have emergency protocols and triage systems as well as the ability to manage the drug supply.
- **Providers** must be seen as receptive to referred cases.
- The **Community** must support the use of the skilled provider and foster BP/CR.
- The **Family** must facilitate access to care, for example, by identifying a walking blood donor for the pregnant woman.
- The **Woman** herself must understand and develop a birth plan with clear actions in the case of a possible hemorrhage.

### PROMOTING COMMUNITY INTERVENTIONS TO PREVENT PPH

# **Igniting Change: Working Together to Prevent PPH**

Ms. Nancy Russell, Director of Social Mobilization with the MNH Program, offered the last presentation of the conference, calling for new approaches, including a paradigm shift from behavior change to social change.

"We should not only work to generate demand for services, but also create a more demanding generation of women who will mobilize for their rights." Ms. Nancy Russell, JHPIEGO Traditional medical models of care have failed to have an impact on maternal health in low-resource settings. New models are needed. To succeed, these new models require champions. Carla AbouZahr of the WHO believes that champions must come from within the health system and the medical community. Their role is to increase knowledge of maternal health and PPH issues through dialogue and critical debate, stimulate debate, and develop reciprocal relationships. Ultimately they can forge partnerships that foster political will and lasting change. In the United Kingdom, a group of 12 individuals got together in the 1700s and decided to address the issue of slavery. Within 20 years, the United Kingdom had banned slavery. Forty years later, other countries had also stopped the practice.

PPH is a complex issue. On one hand, there are known interventions for the prevention and treatment of the condition. The effectiveness of PPH interventions is directly linked to the enabling environment. On the other hand, barriers constrain the use of these interventions. Cultural beliefs play a powerful role and are not easily changed. To be successful, maternal health programs must do more than address medical problems. New partnerships must be built to share technical information. Change will happen only if information is communicated in such a way as to foster dialogue and increase information equity (i.e., make it widely known and understood). To ignite change, we must recognize the need for shared responsibility and collective action. And to sustain change, we must improve knowledge through dialogue, not messages. Dialogue implies increased community control and influence. In striving to effect a social change, we may have to risk relinquishing control.

Table 8. Safe Motherhood Initiative: What Has Changed Since Nairobi (1987)

We have moved away from	То
<ul> <li>Placing responsibility on the woman alone</li> <li>Individual risk assessments at antentatal care</li> <li>Prediction of complications</li> <li>TBAs as primary care providers</li> <li>Focus only danger signs</li> </ul>	<ul> <li>Generalized risk</li> <li>Skilled care at every birth</li> <li>Focus on the birth and the postpartum period</li> <li>BP/CR, informed demand, and collective action</li> </ul>

To promote BP/CR, the MNH Program has developed a framework for collective action, which espouses the idea of shared responsibility. Because safe motherhood works across a continuum of care and a range of players, the framework outlines roles, responsibilities, and actions across key players that include:

- policymakers (establishing the enabling environment),
- facilities (such as hospitals and health centers) and providers (such as nurses and midwives),
- communities, and
- families and women.

Again, the idea of shared responsibility pulls all of these players and interventions together toward improved maternal and newborn survival. First, women, their families, and providers must prepare for normal birth and yet accept that **every** woman risks suffering a life-threatening obstetric complication. Then each individual must be motivated to act rapidly in case of emergency and need for life-saving care during pregnancy, labor, childbirth, and the immediate postpartum and newborn period. Both community-based and health systems have to function to be effective. This functioning requires the involvement and commitment of a broad range of responsible stakeholders, from policymakers to providers, communities, families, and women themselves. All of these stakeholders can ignite and champion social change.

In country programs, field coordinators who have brought communities together to promote birth preparedness have become change agents. In their work, they support women and empower them, their families, and communities to take action to improve complication readiness. This

readiness can take the form of saving schemes and identification of emergency transport or blood donors.

Ms. Russell described the work of the White Ribbon Alliance (WRA), a global movement to disseminate technical information about safe motherhood, promote dialogue and debate from grassroots levels to policymakers, and provide a forum for discussing problems like PPH. Country-level WRAs have been active in igniting change. For example, the WRA in India successfully advocated with the Government of India for the declaration of a national safe motherhood day as well as adoption of a Best Practices Guide with a focus on BP/CR.

### **KEY COMMITMENTS FROM COUNTRY REPRESENTATIVES**

The following table (see **Table 9**) summarizes key commitments regarding PPH in countries represented at the conference. The complete list of country efforts and proposed actions may be found in **Appendix D**.

Table 9. Key Commitments Regarding Postpartum Hemorrhage, by Country

COUNTRY	KEY COMMITMENTS
Afghanistan	<ul> <li>Develop and disseminate a policy statement on prevention of PPH.</li> <li>Add misoprostol to essential drug list.</li> <li>Improve services for births in facilities.</li> <li>Mobilize communities and involve them in safe motherhood activities through community health workers.</li> </ul>
Bangladesh	<ul> <li>Advocate for AMTSL to become the standard of care.</li> <li>Implement birth preparedness and community support mechanisms and encourage NGOs to participate in implementation with Government of Bangladesh.</li> <li>Carry out local research on the use of misoprostol in home births.</li> </ul>
Cambodia	<ul> <li>Disseminate standards for AMTSL in facilities and for misoprostol in home births.</li> <li>Carry out a pilot of use of misoprostol with TBAs and Village Health Support Groups (these groups help link communities with facilities, especially for outreach and community-based activities).</li> <li>Train midwives and expand their use of oxytocin for prevention of PPH.</li> <li>Carry out information, education, and communication (IEC) campaigns to educate on danger signs, with a focus on PPH.</li> </ul>
Egypt	<ul> <li>Improve management of blood and blood components.</li> <li>Advocate for improved infection prevention.</li> <li>Improve referral system for maternal emergencies and increase use of ambulances.</li> </ul>
India	<ul> <li>Recommend allowing auxiliary nurse midwives (ANMs) to give injections for AMTSL.</li> <li>Review ANM workload and increase proportion of time devoted to maternal health.</li> <li>When Indian studies on misoprostol are complete, advocate registration of misoprostol for prophylaxis and treatment of PPH and conduct operations research on how to make it widely available.</li> </ul>
Indonesia	<ul> <li>Advocate for additional recruitment of village midwives to improve coverage.</li> <li>Ensure that AMTSL is in preservice curricula of all schools.</li> <li>Work with Ministry of Women's Affairs to expand successful BP/CR campaigns to new geographical areas.</li> <li>Make misoprostol available to all pregnant women with potential to have an unattended birth.</li> <li>Advocate with district health officials to expand inservice training in basic and comprehensive emergency obstetric care and other elements of the Making Pregnancy Safer initiative.</li> </ul>
Myanmar	<ul> <li>Advocate for updating national standards for maternal health, including the use of AMTSL, and for wider use of uterotonics by midwives.</li> <li>Pilot the use of misoprostol in home births.</li> <li>Register misoprostol for PPH and add to essential drugs list.</li> <li>Use media and community volunteers to increase awareness of PPH and the advantages of a skilled provider at birth (including AMTSL).</li> </ul>
Nepal	<ul> <li>Review and revise standards and protocols for AMTSL; develop job aids and indicators to monitor use.</li> <li>Encourage postpartum stay in facilities.</li> <li>Work with midwifery schools to integrate AMTSL into curricula.</li> <li>Continue to expand efforts in birth preparedness.</li> <li>Discuss and advocate for pilot of misoprostol in one or two districts where there is good antenatal care coverage.</li> </ul>
Philippines	<ul> <li>Integrate AMTSL into safe motherhood policy, standardize training curricula and add to exams, and conduct continuing education on AMTSL standard.</li> <li>Generate position papers to address the question of whether midwives should be able to give oxytocin for AMTSL.</li> <li>Review drug storage practices, meet with drug companies, and develop good storage guidelines.</li> <li>Discuss use of misoprostol with decision-makers; if possible, add to drug formulary.</li> </ul>

COUNTRY	KEY COMMITMENTS
Thailand	<ul> <li>Integrate AMTSL into guidelines, nursing and medical curricula, and hospital accreditation tools.</li> <li>Focus interventions (training, supervision) in provinces with high MMR to encourage universal coverage of AMTSL.</li> <li>Mobilize community effort to encourage greater use of maternal services among minority groups, including community participation.</li> </ul>
Vietnam	<ul> <li>Update national standards for AMTSL, and train teachers and providers at teaching hospitals.</li> <li>Ensure that supervisors know AMTSL standards and can support its use.</li> <li>Explore ways that communities can share cost of uterotonics and other supplies.</li> </ul>
Yemen	<ul> <li>Enhance knowledge of policymakers regarding PPH; review evidence with them.</li> <li>Advocate for updating standards and disseminating them effectively.</li> <li>Integrate AMTSL into preservice curricula, train trainers, and carry out supervision.</li> </ul>

### HIGHLIGHTS AND SUMMARY OF PROGRAM PRIORITIES

"It was nice to learn from a diverse international group the experiences in implementing and promoting AMTSL. The debate around the role of TBAs was interesting. The skill-building sessions were well conducted. The commitment of the entire group in developing strategies for preventing maternal mortality and morbidity from PPH was overwhelming." Conference Participant

A moderator commented that all countries in Asia have vulnerable populations and thus could draw valuable lessons from this conference. At the conclusion of the conference, clear consensus had emerged, as well as some best practices that might be applied from one country to another. These are described below for each of the major areas of PPH programs.

## Preventing PPH with a Skilled Birth Attendant

### Consensus Points

- AMTSL is more effective than expectant management.
- Oxytocin, CCT, and uterine massage should become the established standard for AMTSL.
- Barriers exist, such as:
  - who can provide injections
  - drug procurement and cold chain
- The standard of AMTSL must be incorporated in teaching of physicians, nurses, midwives, etc.

### **Best Practices**

Preventing PPH requires a comprehensive approach that includes policy, drug management, training, community involvement, and sound monitoring of the program.

- Make skilled providers available at the peripheral level.
- Institute performance improvement and clinical supervision of peripheral workers.

- Replicate the Indonesia model of the "alert husband, alert midwife, alert village" campaign that promoted social mobilization for birth preparedness and complication readiness.
- Champions and change agents for any program are critical (the early adopters!).
- When protected from light and heat, injectable uterotonics are much more effective.
- The FIGO/ICM partnership reflects the power of the physician and midwife team for safe motherhood.
- Professional organizations such as obstetrics-gynecology and midwifery associations can ignite change among their members to apply evidence-based practices.

## **Preventing PPH at Home Births**

### **Consensus Points**

- Community midwives attending home births can prevent PPH.
- Misoprostol may be an alternative to AMTSL where there is no skilled provider.

Organizers noted that participants wished to explore further how to implement strategies for birth care and PPH prevention at home births. The Indonesia experience with misoprostol provides a good starting point for other countries, but the latter have to customize interventions to their own settings and discover what will work in their context.

### **Best Practices**

- Start PPH prevention programs by understanding the community.
- **Counseling** is critical.
- Monitoring systems and accountability for use of misoprostol are needed.

### Treatment of PPH

### Consensus Points

- Experience clearly shows that treatment of PPH will always be necessary because not all PPH is preventable.
- Active management of the third stage will not prevent all cases. Therefore, all programs require skilled providers to be present at birth and/or rapid and effective referral systems.

### Possible Future Practices

In the area of treatment of PPH, no clear best practices emerged from the conference. Nevertheless, there are some promising new methods for avoiding invasive procedures such as hysterectomy, and saving lives. Efforts should be made to investigate and develop promising new approaches, such as:

- Condom tamponade
- Non-inflatable anti-shock garment

### Lessons Learned

The themes and approaches emerging from the conference discussions were cross-cutting, and are summarized below.

- Services must be made available where women need them, often in rural and remote areas. Strategies must reach frontline providers at the peripheral level of the healthcare system and expand their reach into the community.
- All programs need to be grounded in the local community and find interventions that are appropriate/acceptable to the cultural context (need for qualitative assessments, pretesting, piloting, etc.). In addition, monitoring of the process (quality of care) and results is essential to track progress and ensure that resources are spent responsibly.
- Registering drugs is not easy, but governments **can** make **any** drugs available (regardless of registration).
- Broad ownership is needed for an intervention to transition to sustainability. We must engage professional organizations, medical and nursing educators, decision-makers at the ministries of health, women's groups, and other advocates to engage in dialogue and debate about the appropriate strategies for reducing maternal mortality and morbidity.
- Champions for change are essential to reach the tipping point. To be a champion, a person must be willing to take a risk.
- Everyone must have information about the risk of maternal death and what actions to take in the case of a complication. We have a shared responsibility.

### **CONCLUSION**

"Women will continue to become pregnant and women will continue to die whether we are ready or not. We have to act now and not delay anymore."

Dr. Mehr Afzoon Mehr Nesaar, Afghanistan All developing countries represented at the conference reported plans to recommend to MOH officials and other policymakers the review of evidence related to use of AMTSL and uterotonic drugs, including misoprostol. Country presentations of proposed actions confirmed a clear commitment to institute AMTSL and use of PPH intervention in areas where access to skilled care is limited. In addition, the need also emerged for additional practical research to test new options for the treatment of PPH.

This conference presented participating countries with an array of practical, field-tested options from which they can choose in order to strengthen/scale up the prevention of PPH. Each country has its own set of conditions and must select appropriate interventions to fit that context.

# APPENDIX A CONFERENCE AGENDA

# PREVENTING POSTPARTUM HEMORRHAGE: FROM RESEARCH TO PRACTICE 20–23 January, 2004, Bangkok, Thailand

**TUESDAY, 20 JANUARY 2004** 

1:00-5:00 Registration

(Foyer, 2<sup>nd</sup> Floor)

2:00–4:00 Meeting of moderators, country team leaders, and rapporteurs

(Ayaret Room)

**Opening Session** 

5:30–6:00 Welcome

(Ballroom III)

Lily Kak (USAID/Washington) Skip Waskin (USAID/Bangkok) Monir Islam (WHO/SEARO)

Harshad Sanghvi (MNH Program/JHPIEGO)

Khunying Kobchitt Limpaphayom (Chulalongkorn University, Thailand)

6:00–6:20 Official opening

Vallop Thainua (Royal Ministry of Public Health, Thailand)

6:20–6:50 Keynote address

Safe motherhood: Taking innovations to scale

Noel McIntosh (JHPIEGO)

6:50–7:00 Vote of thanks

7:00 Dinner

**WEDNESDAY, 21 JANUARY 2004** 

8:30–9:00 Introductions, objectives of meeting, agenda, and expected products

(Ballroom I)

Harshad Sanghvi (MNH Program/JHPIEGO)

Session 1

**Moderator**: Swaraj Rajbhandari (Nepal Family Health Program)

Rapporteur: Emily Westheimer (Gynuity Health Projects)

9:00–9:15 Epidemiology of postpartum hemorrhage

Monir Islam (WHO, SEARO)

9:15-9:30	Active management of the third stage  Harshad Sanghvi (MNH Program/JHPIEGO)
9:30-9:45	Overview of uterotonic drugs  Matthews Mathai (Christian Medical College, Vellore, India)
9:45-10:00	Provider practices regarding prevention of PPH Mario Festin (University of Philippines)
10:00-10:30	Discussion
10:30-11:00	Coffee break
Session 2	
	Moderator: Sompop Limponpsanurak (Chulalongkorn University, Thailand) Rapporteur: Anita Gibson (Nepal Family Health Program)
11:00–11:15	Training in active management of third stage Asmuyeni Muchtar (MNH Program/Indonesia, JHPIEGO)
11:15–11:30	Challenges in introducing active management of third stage of labor at a peripheral hospital  Kusum Thapa (Koshi Zonal Hospital, Nepal)
11:30–11:45	USAID's initiative on prevention of PPH: Addressing policy, logistics, and programming  Mary Ellen Stanton (USAID/Washington)
11:45–12:00	FIGO and ICM joint statement on preventing PPH Walfrido Sumpaico (Asia & Oceana Federation of Ob/Gyn, Philippines) Asmuyeni Muchtar (MNH Program/Indonesia, JHPIEGO)
12:00-12:30	Discussions
12:30-1:30	Lunch (Captain Bush Room, 1st Floor)
Session 3	
1:30-2:20	Concurrent sessions (Participants will sign up for skills labs during registration)
2:30-3:20	Concurrent sessions
3:30-4:20	Concurrent sessions
	Country efforts at preventing PPH (Poster session, Foyer)

# Skills Lab #1: Active management of third stage (Riverside I)

Asmuyeni Muchtar (MNH Program/Indonesia, JHPIEGO) and Kusum Thapa (Koshi Zonal Hospital, Nepal) Demonstration and practice of AMTS on models

# Skills Lab #2: Procedures for treatment of PPH (Riverside I)

Jeffrey Smith (JHPIEGO, USAID/REACH Afghanistan) and Matthews Mathai (Christian Medical College, Vellore, India)

Demonstration of bimanual compression, aortic compression, manual removal of placenta, and suturing of cervical lacerations

# Skills Lab #3: Innovations in treatment of PPH (Riverside II)

Suellen Miller (Women's Global Imperative, University of California), Carol Brees (Memorial Christian Hospital, Sialkot, Pakistan), and Sayeba Akhter (Dhaka Medical College, Bangladesh) Demonstration of use of anti-shock garment and of intrauterine balloons

# Skills Lab #4: Infection prevention and safe injections (Riverside II)

Noel McIntosh (JHPIEGO) and Swaraj Rajbhandari (Nepal Family Health Program)

Demonstration of selected infection prevention techniques and new injection technologies

# Skills Lab #5: Exploring the evidence: Computer lab (Catleya Room)

Pisake Lumbiganon (Khon Kaen University)

Demonstration on how to search the WHO Reproductive Health Library

# Skills Lab #6: Igniting change (Ballroom I)

Nancy Russell (MNH Program/JHPIEGO)

Demonstration and discussion on how to involve stakeholders and increase dialogue for preventing PPH

### 4:30–5:30 First country team meeting

6:00–8:00 Reception hosted by JHPIEGO

### THURSDAY, 22 JANUARY 2004

8:30–8:45 Review of Day One proceedings (Ballroom I)

# Session 4 Preventing postpartum hemorrhage in home births

Moderator: Kurus Coyaji (K.E.M. Hospital, Pune, India) Rapporteur: Rasha Dabash (Gynuity Health Projects)

Effectiveness of misoprostol for prevention of PPH: Review of the current evidence 8:45-9:15

> **Presenter**: Pisake Lumbiganon (Khon Kaen University) **Discussant**: Harshad Sanghvi (MNH Program, JHPIEGO)

9:15-9:30 Oxytocin in Uniject—Current evidence and research in progress

Vivien Tsu (PATH)

9:30-9:45 Preventing PPH in home births: Some lessons from ongoing studies

Jennifer Blum (Gynuity Health Projects)

9:45-10:00 Moving misoprostol out

Beverly Winikoff (Gynuity Health Projects)

10:00-10:30 Discussion

10:30-11:00 **Break** 

Session 5

**Moderator**: Lily Kak (USAID/Washington) **Rapporteur**: *Jennifer Blum (Gynuity Health Projects)* 

11:00-11:45 Results from PPH prevention project in Indonesia

> Gulardi Wiknjosastro (University of Indonesia) Mohammad Zulkarnain (JHPIEGO/Indonesia) Gail Chanpong (JHPIEGO/Baltimore)

Harshad Sanghvi (MNH Program, JHPIEGO)

11:45-12:00 Action plan for implementing large-scale PPH prevention programs in Indonesia

Ieke Irdijiati Syahbuddin (Ministry of Health, Indonesia)

12:00-12:30 Discussion

12:30-1:30 Lunch (Giogio Room, 1st Floor)

Session 6

1:30-3:00 Small group discussions (Six groups)

Promoting and scaling up AMTS

Addressing policy, ensuring availability of uterotonics, and monitoring progress

Moderator: Ashlesha Patel, Chicago

Ensuring AMTS for all: Delivering the service

**Moderator**: Staffan Bergstrom (Karolinksa Institute, Sweden)

Training and supportive supervision for AMTS

**Moderator**: Abdelhadi Eltahir (USAID/Washington)

## Promoting community interventions to prevent PPH

Addressing policy, ensuring availability of misoprostol and monitoring progress

**Moderator**: Beverly Winikoff (Gynuity Health Projects)

Ensuring PPH prevention for all: Community education and distribution of misoprostol

**Moderator**: Gail Chanpong (JHPIEGO)

Training and supportive supervision for community interventions

**Moderator**: Shivaprasad Goudar (J.N. Medical College, Belgaum, India)

3:00–3:30 Tea break

3:30-5:00 Report out and discussion

Session 7

**Moderator**: Djoko Soetikno (JHPIEGO, Indonesia)

Rapporteur: Tami Smith (IntraHealth International, Thailand)

5:15–6:00 Second meeting of country teams

6:30–8:30 Dinner cruise

(Meet on hotel pier at 6:15)

FRIDAY, 23 JANUARY 2004

8:30–8:45 Review of prior day

(Ballroom I)

Session 8

**Moderator:** Chantha Chak (USAID/Cambodia)

Rapporteur: Rajendra Bhadra (Nepal Family Health Program)

8:45–9:00 Addressing the challenges for treating PPH: Emergency obstetric care

Zafarullah Gill (AMDD Program, New York)

9:00–9:15 Getting quality emergency care to remote and rural communities

*Jeffrey Smith (JHPIEGO, USAID/REACH, Afghanistan)* 

9:15–9:30 Innovative treatment approaches

Sayeba Akhter (Dhaka Medical College, Bangladesh)

9:30–9:45 Igniting change: Working together to prevent PPH

Nancy Russell (MNH Program/JHPIEGO)

9:45–10:15 Discussion

10:15–10:45 Tea break

10:45-12:30	Development of action items: Third meeting of country teams
12:30-1:30	Lunch (Giorgio Room, 1st Floor)
Session 9	
	Moderator: Jeffrey Smith (JHPIEGO, USAID/REACH, Afghanistan) Rapporteur: Anne Pfitzer (JHPIEGO)
1:30-3:00	Presentation of country actions
3:00-3:30	Tea break
3:30-4:15	Presentation of country actions (continued)
4:15-4:30	Summary Anne Pfitzer (JHPIEGO)
4:30-4:45	Call to action and closing remarks  Lily Kak, Mary Ellen Stanton, Mehr Afzoon, Harshad Sanghvi

# APPENDIX B CONFERENCE PARTICIPANTS

### **AFGHANISTAN**

Jeffrey M. Smith, JHPIEGO/USAID/REACH
Hekmat Jami, Malalai Maternity Hospital
Mehr Afzoon Mehr Nesaar, Ministry of Health
Ismael M. Ashraf, Provincial Hospital Mazar
Saaida Said Mohammed, Traditional Birth Attendant

Ellen Elizabeth Lynch, USAID/IOM

Ahmadullah Ahmadzai, USAID/REACH

Razia Naeem Khaliqi, USAID/REACH

### **BANGLADESH**

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Ang Sareth, National Mother and Child Health Center

Lam Phirun, National Mother and Child Health Center

Pa La Ine, Pursat Referral Hospital

Ki Kean Hong, Pursat Referral Hospital

Sam Sochea, Reproductive and Child Health Alliance

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Muhammad Naguib, John Snow Inc./USAID

Sameer Noshy Shenouda Al-Raheb, John Snow Inc./USAID

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Narika Namshum, Ministry of Health and Family Welfare

Rashmi Asif, PRIME/IntraHealth International

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Rita Joshi, Nepal Family Health Program
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# **APPENDIX C**





# Joint Statement Management of the Third Stage of Labour to Prevent Post-partum Haemorrhage

# International Confederation of Midwives (ICM) International Federation of Gynaecologists and Obstetricians (FIGO)

ICM and FIGO are key partners in global Safe Motherhood efforts to reduce maternal death and disability in the world. Their mission statements share a common commitment in promoting the health, human rights and well-being of all women, most especially those at greatest risk for death and disability associated with childbearing. FIGO and ICM promote evidence-based, effective interventions that, when used properly with informed consent, can reduce the incidence of maternal mortality and morbidity in the world.

Severe bleeding is the single most important cause of maternal death worldwide. More than half of all maternal deaths occur within 24 hours of delivery, mostly from excessive bleeding. Every pregnant woman may face life-threatening blood loss at the time of delivery; women with anaemia are particularly vulnerable since they may not tolerate even moderate amounts of blood loss. Every woman needs to be closely observed and, if needed, stabilized during the immediate post-partum period.

Upon review of the available evidence, FIGO and ICM agree that active management of the third stage of labour is proven to reduce the incidence of post-partum haemorrhage, the quantity of blood loss, and the use of blood transfusion.

Active management of the third stage of labour should be offered to women since it reduces the incidence of post-partum haemorrhage due to uterine atony.

Active management of the third stage of labour consists of interventions designed to facilitate the delivery of the placenta by increasing uterine contractions and to prevent PPH by averting uterine atony. The usual components include:

- Administration of uterotonic agents
- Controlled cord traction
- Uterine massage after delivery of the placenta, as appropriate.

Every attendant at birth needs to have the knowledge, skills and critical judgment needed to carry out active management of the third stage of labour and access to needed supplies and equipment.

In this regard, national professional associations have an important and collaborative role to play in:

- Advocacy for skilled care at birth;
- Dissemination of this statement to all members of the organisation and facilitation of its implementation;
- Public education about the need for adequate prevention and treatment of post-partum haemorrhage;
- Publication of the statement in national midwifery, obstetric and medical journals, newsletters and websites;
- Address legislative and other barriers that impede the prevention and treatment of postpartum haemorrhage;
- Incorporation of active management of the third stage of labour in national standards and clinical guidelines, as appropriate;
- Incorporation of active management of the third stage into pre-service and in-service curricula for all skilled birth attendants;
- Working with national pharmaceutical regulatory agencies, policymakers and donors to assure that adequate supplies of uterotonics and injection equipment are available.

# MANAGEMENT OF THE THIRD STAGE OF LABOUR TO PREVENT POST-PARTUM HAEMORRHAGE

### **HOW TO USE UTEROTONIC AGENTS**

- Within one minute of the delivery of the baby, palpate the abdomen to rule out the presence of an additional baby(s) and give oxytocin 10 units IM. Oxytocin is preferred over other uterotonic drugs because it is effective 2-3 minutes after injection, has minimal side effects and can be used in all women.
- If oxytocin is not available, other uterotonics can be used such as: ergometrine 0.2 mg IM, syntometrine (1 ampoule) IM or misoprostol 400-600 mcg orally. Oral administration of misoprostol should be reserved for situations when safe administration and/or appropriate storage conditions for injectable oxytocin and ergot alkaloids are not possible.
- Uterotonics require proper storage:
  - o Ergometrine: 2-8°C and protect from light and from freezing.
  - O Misoprostol: room temperature, in a closed container.
  - o Oxytocin: 15-30°C, protect from freezing
- Counselling on the side effects of these drugs should be given.

Warning! Do not give ergometrine or syntometrine (because it contains ergometrine) to women with pre-eclampsia, eclampsia or high blood pressure.

## HOW TO DO CONTROLLED CORD TRACTION

- Clamp the cord close to the perineum (once pulsation stops in a healthy newborn) and hold in one hand.
- Place the other hand just above the woman's pubic bone and stabilize the uterus by applying counter-pressure during controlled cord traction.
- Keep slight tension on the cord and await a strong uterine contraction (2-3 minutes).
- With the strong uterine contraction, encourage the mother to push and very gently pull downward on the cord to deliver the placenta. Continue to apply counter-pressure to the uterus.
- If the placenta does not descend during 30-40 seconds of controlled cord traction do not continue to pull on the cord:
  - o Gently hold the cord and wait until the uterus is well contracted again;
  - o With the next contraction, repeat controlled cord traction with counter-pressure.

Never apply cord traction (pull) without applying counter traction (push) above the pubic bone on a well-contracted uterus.

- As the placenta delivers, hold the placenta in two hands and gently turn it until the membranes are twisted. Slowly pull to complete the delivery.
- If the membranes tear, gently examine the upper vagina and cervix wearing sterile/disinfected gloves and use a sponge forceps to remove any pieces of membrane that are present.
- Look carefully at the placenta to be sure none of it is missing. If a portion of the maternal surface is missing or there are torn membranes with vessels, suspect retained placenta fragments and take appropriate action (ref Managing Complications in Pregnancy and Childbirth).

## **HOW TO DO UTERINE MASSAGE**

- Immediately massage the fundus of the uterus until the uterus is contracted.
- Palpate for a contracted uterus every 15 minutes and repeat uterine massage as needed during the first 2 hours.
- Ensure that the uterus does not become relaxed (soft) after you stop uterine massage.

In all of the above actions, explain the procedures and actions to the woman and her family.

Continue to provide support and reassurance throughout.

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### ICM/FIGO GLOBAL INITIATIVE ON THE PREVENTION OF POST-PARTUM HAEMORRHAGE

"We need to stop the deaths of 200,000 women each year from bleeding during childbirth"

A. Acosta, FIGO President November 7<sup>th</sup>, 2003 Santiago, Chile

## **TEN KEY ACTIONS**

### ICM and FIGO will:

- Disseminate the joint statement to all national societies of obstetrician-gynaecologists and midwives' associations and encourage the national groups to disseminate it to their members.
- 2. Obtain support for the joint statement from agencies in the field of maternal and neonatal health care, such as UN agencies, development and others.
- 3. Recommend that this Global Initiative on the prevention of PPH be integrated into the curricula of medical, midwifery and nursing schools.
- 4. Recommend that the Global Initiative be adopted by health policy makers and politicians.

## ICM and FIGO will work together toward ensuring that:

- 5. Every mother giving birth anywhere in the world will be offered active management of the third stage of labour for the prevention of PPH.
- 6. Every skilled attendant will have training in active management of the third stage of labour and in techniques for the treatment of PPH.
- 7. Every health facility where births take place will have adequate supplies of uterotonic drugs, equipment and protocols for both the prevention and treatment of PPH.
- 8. Blood transfusion facilities are available in centres that provide comprehensive health care (secondary and tertiary levels of care).

- 9. Physicians are trained in simple conservative techniques such as compression sutures and devascularisation.
- 10. Promising new drugs and technologies for the prevention and treatment of PPH, such as the tamponade technique, are evaluated.

## APPENDIX D COUNTRY EFFORTS AND PROPOSED ACTIONS

	CONTEXT EFFORTS TO DATE		PROPOSED ACTION
Afghanistan	<ul> <li>Population: 24 million</li> <li>MMR: 1,600/100,000 live births</li> <li>Total Fertility Rate (TFR): 6.9</li> <li>Contraceptive Prevalence Rate: 2%</li> <li>Coverage of skilled attendance: 5%</li> <li>Shortage of female health providers; e.g., in Nooristan province, 43:1 ratio male to female</li> <li>Low literacy, particularly among women</li> <li>90% births at home</li> <li>48% of deaths of women of reproductive age are from maternal causes</li> <li>39% of maternal deaths are due to hemorrhage</li> </ul>	<ul> <li>Strong political commitment for improved maternal health, prevention of PPH</li> <li>Basic package of health services defined and includes EmOC</li> <li>Establishment of Women's and Reproductive Health unit within MOH</li> <li>Development of national reproductive health strategy and clinical standards</li> <li>Donor support: e.g., regional centers of excellence for EmOC and rehabilitation of midwifery schools</li> </ul>	<ul> <li>Improve safe motherhood         <ul> <li>EmOC</li> <li>Skilled attendance</li> <li>Antenatal care</li> </ul> </li> <li>Increase coverage of family planning services         <ul> <li>Short term</li> </ul> </li> <li>Focus on high % of home births         <ul> <li>Establish standards of care for home birth</li> </ul> </li> <li>Establish working group on PPH         <ul> <li>Develop/disseminate policy statement on prevention of PPH             <ul> <li>Add misoprostol to essential drug list</li> </ul> </li> </ul> </li> <li>Facility births: AMTSL, supply of oxytocin, supervision, monitoring, reporting</li> <li>Home births: Social mobilization, community involvement, community health workers as health promoters, pilot and evaluate misoprostol for prevention of PPH</li> </ul>

	CONTEXT	EFFORTS TO DATE	PROPOSED ACTION
Bangladesh	<ul> <li>Population: 147 million</li> <li>MMR: 320/100,000 live births</li> <li>15% births attended by skilled provider</li> <li>90% births at home</li> <li>Unmet need for EmOC: 85%</li> <li>26% of maternal deaths caused by hemorrhage</li> <li>TFR: 3.46/CPR: 54%</li> <li>Female literacy: 30%</li> <li>Life expectancy at birth: 60.5</li> <li>IMR: 51/1,000 live births</li> </ul>	<ul> <li>Women-Friendly Hospital Initiative</li> <li>Training of doctors, nurses, paramedics working in ob/gyn:         <ul> <li>EmOC</li> <li>Management of obstetric emergency and trauma</li> <li>Safe childbirth</li> </ul> </li> <li>Training of blood transfusion technicians</li> <li>Provision of equipment and drugs</li> <li>Strengthening and decentralization of services</li> <li>Improving linkages to referral care</li> <li>Raising community awareness</li> <li>Establishing community support mechanisms</li> <li>Use of innovative methods, e.g., hydrostatic balloon</li> </ul>	<ul> <li>Facilitate policy dialogue (meetings, workshop, seminar etc.)</li> <li>Initiate consensus building efforts on standards and guidelines on AMTSL</li> <li>Advocacy and dissemination workshops to share information on standards</li> <li>Preparation of guideline, protocol on PPH management</li> <li>Development of supervision and monitoring checklists</li> <li>The checklist incorporated in existing monitoring system</li> <li>Replicate the learnings of Women-Friendly Hospital Initiative, especially stakeholder participation in other services/facilities</li> <li>Government will implement the Birth Preparedness and Community Support mechanism initiatives through its existing structures, and encourage other NGOs to support the Government of Bangladesh efforts</li> <li>More research on misoprostol</li> <li>Policy advocacy for home distribution of misoprostol, based on evidence</li> </ul>

	CONTEXT	EFFORTS TO DATE	PROPOSED ACTION
Cambodia	<ul> <li>Population: 14 million</li> <li>MMR: 437/100,000 live births</li> <li>80% births at home</li> <li>34% attended by skilled provider</li> <li>Female literacy: 57%</li> <li>TFR: 4.77/CPR: 24%</li> <li>IMR: 97/1,000</li> <li>Life expectancy at birth: 57.4</li> </ul>	<ul> <li>Policy on ATMSL exists</li> <li>Still challenge to operationalize policy</li> <li>Misoprostol is addressed in Safe Motherhood 5-year Action Plan; there is no protocol for using misoprostol for PPH</li> <li>Misoprostol is incorporated in national essential drug list, but for indications of safe abortion and intrauterine fetal death only</li> <li>Application of AMTSL is limited only to midwives who have received pre- and inservice midwifery training (30% of midwives)</li> <li>Limited recognition of PPH danger signs</li> <li>Limited information on available services</li> </ul>	<ul> <li>Need to clarify the status of the protocol on using misoprostol in preventing PPH (short term)</li> <li>Organize a national workshop to discuss and disseminate protocol on AMTSL, including oxytocin in maternity, and include using misoprostol for home deliveries—TA from outside (short term)</li> <li>Pilot on using misoprostol through TBA/village health support groups (VHSGs) (medium term)</li> <li>Increase number of midwives trained on AMTS (short and medium term)</li> <li>Increase use of oxytocin by trained midwives (medium term)</li> <li>Strengthen referral system (short and medium term)</li> <li>Update AMTS curriculum and supervision guidelines</li> <li>Strengthen supervision post-training (short and medium term)</li> <li>Develop training curriculum and plan on using misoprostol for TBAs and VHSG (medium term)</li> <li>Implement guidelines</li> <li>Organize workshop among stakeholders on PPH (prevention and treatment) (short term)</li> <li>Modify IEC strategy/materials by giving priority to PPH (medium term)</li> <li>Promote appropriate IEC related to danger signs (medium term)</li> <li>Community support to referral system (medium term)</li> <li>Community support to referral system (medium term)</li> </ul>

	CONTEXT	EFFORTS TO DATE	PROPOSED ACTION
Egypt	<ul> <li>Population: 69 million</li> <li>Female literacy rate: 44%</li> <li>MMR: 84/100,000</li> <li>52% birth occur at home</li> <li>65% attended by a skilled provider</li> <li>Drop in PPH-related maternal deaths</li> <li>TFR: 3/CPR: 56%</li> <li>27 governorates of which 17 not yet covered by Healthy Mother/Healthy Baby project</li> <li>Geographical discrepancies in maternal health statistics (Lower Egypt has poorer statistics) as well as in vulnerable populations, such as slum dwellers</li> <li>Nurse midwife not allowed to give drugs without doctor</li> </ul>	facilities  Continuous quality improvement process instituted  Strengthening and decentralization of services Improving linkages to referral care  National Maternal Mortality Surveillance System	<ul> <li>Develop safe motherhood committees in Lower Egypt to expand availability of oxytocin</li> <li>Expand continuous quality improvement system</li> <li>Advocate for decentralized management of PPH</li> <li>Improve management of blood and blood components in facilities; provide them with equipment to separate blood components; encourage screening of blood donors rather than units of blood; increase use of ELISA tests</li> <li>Create awareness of infection risks and improve infection prevention, including availability of affordable supplies</li> <li>Implement referral system for maternal emergencies and increase availability of ambulances</li> <li>Conduct operational research for new interventions/ technologies, e.g., misoprostol, Uniject, non-inflatable anti-shock garment</li> </ul>
India	<ul> <li>Population: 1 billion</li> <li>Female literacy rate: 42%</li> <li>TFR: 3.1/CPR: 47%</li> <li>MMR: 540/100,000 live births</li> <li>43% of births attended by skilled provider</li> <li>ANC coverage: 60%</li> </ul>	<ul> <li>National government committed to reduce MMR (both in health plan and population plan)</li> <li>11 April is Safe Motherhood Day in India</li> <li>National Reproductive Healthcare program includes emphasis on skilled attendants at birth, EmOC, strengthened FRUs and PHCs and public/private partnerships</li> <li>Training of medical officers in Anesthesia for EmOC, EmOC, also improving blood supply</li> <li>Use of strategic communication and alliances, including with local governments</li> </ul>	<ul> <li>Recommend improving skills of ANMs and allowing them to provide oxytocin for AMTSL</li> <li>Refocus workload of ANMs so that they have more time for maternal health (identify helper ANMs or other cadres to carry out outreach activities)</li> <li>Await results of ongoing studies of use of misoprostol for PPH prevention. Assuming results are good:</li> <li>Advocate for registration of misoprostol for prophylaxis and treatment of PPH</li> <li>Conduct operations research on how to make it widely available safely</li> </ul>

		CONTEXT	EFFORTS TO DATE	PROPOSED ACTION
Indonesia	•	Population: 204 million MMR: 307/100,000 live births Located on 17,000 islands (but 59% live in Java and Bali) 30 provinces 343 districts Hemorrhage accounts for 28% of maternal deaths 60% of births are at home 66% are attended by skilled providers Making Pregnancy Safer policies strive for all women to have access to skilled provider during pregnancy, childbirth, and postpartum period and all women and newborns should have access to referral care in case of complications	<ul> <li>Where there are skilled providers</li> <li>PPH through AMTSL already in policy; however, only 40% midwives trained in AMTSL</li> <li>Community activities to enhance birth preparedness and complication readiness existing in some areas</li> <li>When there is no skilled provider</li> <li>Misoprostol for unattended births accepted by policymakers</li> <li>PPH treatment</li> <li>Integrated in Making Pregnancy Safer Initiative</li> </ul>	<ul> <li>Where there are skilled providers</li> <li>Advocate for the recruitment of more midwives to improve coverage in villages</li> <li>Ensure AMTSL standard in preservice curricula</li> <li>Carry out inservice training</li> <li>Strengthen supervision system at district-level</li> <li>Advocate with Ministry of Women's Affairs to expand BP/CR to additional communities</li> <li>When there is no skilled provider</li> <li>Make misoprostol available to all pregnant women with potential to have an unattended birth (in the short term, expand misoprostol coverage to four districts/provinces)</li> <li>PPH treatment</li> <li>Advocate for integration of Making Pregnancy Safer in district health plan</li> <li>Stress need for basic and comprehensive emergency obstetric care training</li> <li>Upgrade midwifery curricula including teacher training school</li> </ul>

CONTEXT EFFORTS TO DATE		PROPOSED ACTION		
Population: 52 million 324 townships, 2,548 wards, 65,148 villages MMR: 110/100,000 urban and 190/100,000 rural (170 overall) MCH unit in MOH, down to township level Manpower: 2,550 LHV and 14,094 midwives 5 Institutes of Medicine 2 Institutes of Nursing, as well as nursing, midwifery, and domiciliary midwife training schools Each hospital has its own protocols—no national standards Auxiliary midwives not allowed to give injections	Training of midwives in safe childbirth practices including AMTS; however, midwives allowed to perform three components only under MD supervision	<ul> <li>Advocacy and discussions with ob/gyns and MOH to update and adopt national standards for maternal health, including AMTSL</li> <li>Establish AMTSL as the standard in hospitals</li> <li>Advocate for wider use of uterotonics by midwives</li> <li>Update curricula and establish competency-based training as methodology for training</li> <li>Pilot the use of misoprostol for home births</li> <li>Register misoprostol for PPH and add to essential drug list</li> <li>Procure and distribute both oxytocin and misoprostol</li> <li>Use media and community volunteers to increase awareness of PPH and advantages of skilled provider (AMTSL)</li> </ul>		

	CONTEXT	EFFORTS TO DATE	PROPOSED ACTION
Nepal	<ul> <li>Population: 22.4 million</li> <li>MMR: 830/100,000 live births</li> <li>80% births at home</li> <li>11% births attended by a skilled provider</li> <li>Only 9% of births are in hospitals</li> <li>Only 13% of pregnant women receive antenatal care</li> <li>Hemorrhage accounts for 46% of maternal deaths</li> <li>TFR: 4.6 CPR 39%</li> <li>Total adult literacy rate: 41%</li> <li>Difficult geographical topography</li> <li>High prevalence of anemia</li> <li>Lack of blood transfusion facilities</li> </ul>	<ul> <li>Preventing PPH in health facilities</li> <li>Birth preparedness/complication readiness efforts</li> <li>Efforts to reduce anemia</li> <li>Training of providers in AMTSL, use of emergency obstetric care kits, and avoiding unnecessary procedures</li> <li>Preventing PPH in home births</li> <li>Initial discussions about misoprostol in community settings</li> <li>Exploration of use of Uniject filled with oxytocin</li> <li>Teaming TBAs and other unskilled attendants with skilled providers</li> </ul>	<ul> <li>Preventing PPH in health facilities</li> <li>Consensus building Safe Motherhood Subcommittee</li> <li>Build partnerships with professional organizations</li> <li>Nepal Society for Ob/Gyns, Nepal Association of Nursing)</li> <li>Review and revise standards and protocols for AMTSL and develop job aids</li> <li>Encourage postpartum stay in facilities</li> <li>Develop indicators for monitoring AMTSL</li> <li>Work with midwifery schools to integrate AMTSL in preservice curricula</li> <li>Strengthen existing basic emergency obstetric care (10 sites/year)</li> <li>Refresher training for all MCHW/ANM</li> <li>Expand birth preparedness</li> <li>Preventing PPH in home births</li> <li>Initiate discussion of use of misoprostol</li> <li>Pilot in 1–2 district where there is good antenatal care coverage</li> </ul>
Pakistan	<ul> <li>Population: 145 million</li> <li>MMR: 200/100,000 live births</li> <li>70% births at home</li> <li>20% births attended by skilled provider</li> <li>Total adult literacy rate: 43%</li> <li>TFR: 5.2/CPR: 17%</li> </ul>	Preventing PPH in health facilities	<ul> <li>Preventing PPH in health facilities</li> <li>Build partnerships with professional organizations (Pakistan Medical Association, Pakistan Association of Ob/Gyns) and other stakeholders</li> <li>Review and revise standards and protocols for AMTSL and develop job aids</li> <li>Encourage postpartum stay in facilities</li> <li>Develop indicators for monitoring AMTSL</li> <li>Work with midwifery schools to integrate AMTSL into preservice curricula</li> <li>Strengthen public/private partnerships</li> <li>Strengthen existing basic emergency obstetric care sites (10 sites/year)</li> <li>Refresher training for all LHVs/ANMs</li> <li>Preventing PPH in home births</li> <li>Initiate discussion of use of misoprostol</li> </ul>

	CONTEXT	EFFORTS TO DATE	PROPOSED ACTION
Philippines	<ul> <li>Population: 77 million</li> <li>MMR: 172/100,000</li> <li>Female literacy rate: 95%</li> <li>TFR: 3.4/CPR: 47%</li> <li>65% of births occur at home</li> <li>57% births attended by skilled provider</li> <li>PPH leading cause of maternal death</li> <li>AMTSL not commonly practiced</li> <li>Oxytocin is available</li> <li>Methylergometrine more commonly used for PPH</li> <li>"Eminence is more powerful than evidence"</li> <li>Regulation that midwives can give oxytocin only after the delivery of the placenta</li> <li>Misoprostol pulled out of the country because of misuse</li> </ul>	Safe motherhood program in place	<ul> <li>Integrate AMTSL into safe motherhood policy</li> <li>Generate position papers to address question of whether midwives should be able to give oxytocin for AMTSL</li> <li>Review drug storage practices, meet with drug companies, and develop good storage guidelines</li> <li>Discuss use of misoprostol with decision-makers; if possible, add to drug formulary</li> <li>Work with ob/gyn colleagues to standardize AMTSL training, introduce in continuing medical education workshops and conferences, adapt education curricula and add to medical examinations</li> <li>Meet with DOH and women's groups and conduct activities to give information on PPH</li> </ul>
Thailand	<ul> <li>Population: 63 million</li> <li>Some success in reducing MMR (44/100,000 live births), but still variation between regions</li> <li>85% births are attended by skilled provider</li> <li>TFR: 2.0/CPR: 72%</li> <li>Female literacy rate: 94%</li> <li>Minority groups have low use of maternal health services—geographical difficulties, mountains, islands, cultural barriers</li> </ul>	Management of PPH already in guidelines, but not AMTSL; currently, providers are taught to give oxytocin after delivery of placenta and only 10% perform CCT	<ul> <li>Integrate AMTSL in guidelines, nursing, medical curricula, hospital accreditation tools</li> <li>Focused interventions (training, supervision) in high MMR provinces to encourage universal coverage of AMTSL</li> <li>Community effort to encourage greater use of maternal services among minority groups, including community participation</li> </ul>

	CONTEXT EFFORTS TO DATE		PROPOSED ACTION
Vietnam	<ul> <li>Population 79 million</li> <li>MMR relatively low at 95/100,000 live births</li> <li>70% births attended by skilled attendant</li> <li>CPR: 74%</li> <li>Female literacy: 91%</li> <li>Lack of commitment and funding for maternal health</li> <li>AMTSL is not standard</li> </ul>		<ul> <li>Long term</li> <li>Update national standards to include AMTSL</li> <li>Train teachers and providers of teaching hospitals</li> <li>Ensure that supervisors know and can supervise AMTSL</li> <li>Look at ways communities can share cost of uterotonics and other supplies</li> <li>Short term</li> <li>Pilot AMTSL</li> <li>Prepare curricula, trainers, and course materials for AMTSL</li> <li>Adapt supervision tools to include AMTSL</li> <li>Obtain support for PPH prevention from decision-makers</li> </ul>
Yemen	<ul> <li>Population: 19 million</li> <li>MMR 1,000–1,400 per 100,000 live births</li> <li>Population dispersed—73% in rural areas</li> <li>84% births at home</li> <li>22% attended by skilled provider</li> <li>TFR: 6.5/CPR: 21%</li> <li>Female literacy 32%</li> <li>Standards are not clear, AMTSL not applied universally</li> <li>Belief that oxytocin causes retained placenta</li> <li>Mothers stay in facility only 30 minutes after birth</li> </ul>	<ul> <li>Increase in training of midwives</li> <li>Ongoing efforts to improve quality of care (development of standards, guidelines, inservice training, review of curricula)</li> <li>Development of District Health System (enhancing decentralization, community participation, cost sharing)</li> <li>Health services management improvement efforts</li> <li>Support from international organizations and NGOs</li> <li>Private sector expands health coverage</li> <li>Efforts to improve the district hospitals' capacity to provide emergency obstetric care as well as referral system</li> </ul>	<ul> <li>Enhance knowledge of policymakers; workshops present data, especially from Yemen but other countries too</li> <li>Creation of multi-disciplinary groups, difficult, but maybe through medical associations, donors</li> <li>Involving donors in financing</li> <li>Update standards and disseminate them</li> <li>Partnerships with professional societies</li> <li>Integrate AMTSL in preservice curricula, train trainers, supervision</li> </ul>

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